

A study on eccentric occluder via ultra minimal incision of Double committed ventricular septal defect

Qiang Gao¹, Jie Jin¹, Zewei Zhang¹, Lianglong Ma¹, Jianhua Li¹, and Jiangen Yu¹

¹Affiliation not available

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Abstract

Object: To compare the clinical data of sternotomy and left intercostals incision, combined with the literature, to provide the best surgical incision for committed subarterial ventricular septal defect(DCS-VSD). **Methods:** From July 2016 to July 2020, a total of 117 cases of occlusion surgeries for DCSVSD, which guided by transoesophagel echocardiography(TEE) were completed, including 34 cases with sternotomy incision and 83 cases with left intercostal incision. **Statistics and analysis of the operation and follow-up.** **Results:** 115 cases successfully occluded, the successful rate was 98.29%, and 1 case failed in each group. Pericardial effusion occurred in 5 children after the drainage device was removed, and the pericardial effusion disappeared after diuretic treatment. There was no statistical difference between the two groups in operation time, occlusion time, thoracotomy time and postoperative hospital stay. All the children recovered and were discharged from the hospital, and were followed up for 2-30 months after operation. **Conclusion:** TEE-guided intercostal DCS-VSD occlusion is safe and effective. There is no statistical difference between two approach with the operation time, chest opening and closing time, occluder placing time, and postoperative hospital staying. At the same time, the surgical incision by intercostal incision is smaller and the operation invasion is less, it is a surgical approach which worth to develop.

A study on eccentric occluder via ultra minimal incision of Doubly Committed Subarterial Ventricular Septal Defects

Qiang Gao[1], Jie Jin[1], Zewei Zhang[1], Lianglong Ma[1], Jianhua Li[1], Jiangen Yu[1]

[1]: Department of Cardiac Surgery& Heart Center, The Children's Hospital, Zhejiang University School of Medicine, National Clinical Research Center for Child Health, Hangzhou 310052, China

Corresponding author: Zhang Zewei, Email:zeweiz@zju.edu.cn

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Abstract: **Object:** To compare the clinical data of sternotomy and left intercostals incision, combined with the literature, to provide the best surgical incision for committed subarterial ventricular septal defect(DCS-VSD). **Methods:** From July 2016 to July 2020, a total of 117 cases of occlusion surgeries for DCSVSD, which guided by transoesophagel echocardiography(TEE) were completed, including 34 cases with sternotomy incision and 83 cases with left intercostal incision. **Statistics and analysis of the operation and follow-up.** **Results:** 115 cases successfully occluded, the successful rate was 98.29%, and 1 case failed in each group. Pericardial effusion occurred in 5 children after the drainage device was removed, and the pericardial effusion disappeared after diuretic treatment. There was no statistical difference between the two groups in operation

time, occlusion time, thoracotomy time and postoperative hospital stay. All the children recovered and were discharged from the hospital, and were followed up for 2-30 months after operation. Conclusion: TEE-guided intercostal DCS-VSD occlusion is safe and effective. There is no statistical difference between two approach with the operation time, chest opening and closing time, occluder placing time, and postoperative hospital staying. At the same time, the surgical incision by intercostal incision is smaller and the operation invasion is less, it is a surgical approach which worth to develop.

Keywords: Doubly Committed Subarterial Ventricular Septal Defects; minimally invasive occlusion; Interventional surgery

Ventricular septal defect is the most common congenital heart diseases. As one kind of VSDs doubly committed subarterial ventricular septal defect (DCS-VSD) is very high incidence in Asians, reaching 25% [1]. For a long time, DCS-VSD can only be treated by cardiopulmonary bypass surgery. Although there have been reports of catheter interventional treatment, the operation is complicated and the failure rate is high. Very few hospitals carry out [2]. In recent years, TEE guided surgical occlusion of ventricular septal defect has made great progress. The application of eccentric occluder has made minimally invasive interventional therapy of DCS-VSD widely available [3,4,5]. TEE-guided transthoracic occlusion, without cardiopulmonary bypass cardiopulmonary bypass, and no radiation, is an excellent surgical stratege. At present, the surgical approaches for DCS-VSD occlusion surgery mainly include sternum incision, intercostal incision on the left side and underarm incision [3, 6, 7, 8]. This study reports a comparison of the two surgical approaches, which are sternum incision and intercostal incision, combined with the literature, to analyze their respective advantages and disadvantages, and discuss which method is a better surgical approach.

Materials and Methods

Clinical data

From July 2016 to July 2020, we implemented 117 cases of DCS-VSD closure. 34 children underwent by sternotomy incision, including 23 males and 11 females, aged 13-163 months (Median age 34 months), weight 7.6-49.8 (15.61±8.07) kg, diameter of VSD is about 2.2-8 (4.00±1.44) mm. There were 83 children underwent by small incision on the left intercostal, including 57 males and 26 females, aged 12-137 months (Median age 35 months), weighing 8.9-28(15.14±4.69)kg, and diameter of VSD is about 2-6(3.80±1.03) mm.

Methods

Institutional Review Board: This study is a retrospective study of clinical surgery and does not require IRB approval

Fully inform the child's guardian of the operation method and operation risk before the operation, and sign the operation informed consent.

Preventive use of cefuroxime during perioperative period. The children were routinely anesthetized, and TEE was used to assess the size of DCS-VSD and the performance of the aortic valve. If the size of DCS-VSD is appropriate, and the right aortic valve is slightly prolapsed or the aortic valve is slightly regurgitated, consider occlusion, otherwise we switched to open-heart surgery. We chosed the size of occluder as diameter of DCS-VSD+ 2[Fig 1,2], which is eccentric (Produced by Shanghai Shape Memory Alloy Co., Ltd). The operation is performed by 3 senior chief physicians, and the surgical incision is determined according to the habits of the chief surgeon.

After sterilized drapes, the sternum incision is made in the lower part of the sternum, normal is about 3-4cm, then the sternum is sawed into the mediastinum, pericardium is opened and suspended. A small intercostal incision is generally made on the left 2-3th intercostal space of the sternum, and is about 1cm[Fig 3]. After the thymus is pushed aside, the pericardium can be opened. After exposing the heart, we use tweezers to locate the position of puncture on the anterior wall of the right ventricle. We choose the position for puncture on right ventricular surface, which is closest and minimum angle to the shunt flow of VSD. The suture purse is reserved on the puncture site. 1mg/kg heparinized after the trocar is punctured in the purse.

After removing the inner core, the steel wire is inserted through the lumen of the trocar. Under the guidance of TEE, the wire was delivered to the left ventricle through the defect. Then we withdraw the trocar, deliver the delivery sheath to the left ventricle along the wire, then exit the wire and the inner sheath of the delivery tube, then dock the sheath with the occluder and the delivery sheath. Under TEE monitoring, we release the left disc first, then observe the position of the eccentric marker, and turn the occluder clockwise to make the marker face down and aim at the distal end of the aortic valve. We pull back the left disc to make it close to the ventricular septum, continue to retract the sheath to the right ventricle, and then release the occluder waist and right ventricular disc[Fig 4]. TEE simultaneously checked for residual shunt, outflow tract obstruction, aortic pulmonary valve regurgitation, and ECG monitoring for arrhythmia. If any abnormality is found, adjust or replace the occluder immediately. If there is no abnormality, the occluder is released after the push-pull test. Withdraw the delivery tube and tie the purse. After checking that there is no bleeding, place a drainage device[Fig 5] and close the chest. Take aspirin anticoagulant treatment for 3 months after operation.

Postoperative cardiac echo, chest radiographs and electrocardiograms to assess cardiac function, valve regurgitation, occluder status, and the presence of complications such as arrhythmia and pericardial effusion.

Statistical analysis

Data on age was expressed as the range and median. Data on weight, DCVSD size, procedure relating time and the length of hospital stay were expressed as range and the mean \pm standard deviation . All data were analysed using SPSS 19.0 statistical software.

Results

117 cases of DCS-VSD were successfully occluded in 115 cases, the success rate was 98.29%, and there was one case in each group failed. One child was 11 months old, with a DCS-VSD, size of 6 mm, using a small intercostal incision, and using a No. 8 eccentric occluder during the operation. There was still a residual shunt of 2.5 mm, and he was changed to operate cardiopulmonary bypass surgery. One child was 49 months old, with a DCS-VSD, size of 7 mm, using a sternum incision, and using a No. 9 eccentric occluder during the operation. The occlude was displaced during the releasing of the occluder and was changed to operate cardiopulmonary bypass surgery[Fig 6]. The occluding of the other children went smoothly. There were no residual shunts, aggravated valve regurgitation, outflow tract obstruction, and no serious complications such as complete atrioventricular block. The total operation time of the sternal incision group was 18-71 (46.58 \pm 13.58) min, of which the occluding time was 5-38 (13.83 \pm 9.17) min, chest switching time 24-54 (36.00 \pm 9.80) min. Three children had pericardial effusion after operation, the length of postoperative hospital stay was 7 days,11 days,and 20 days. The postoperative postoperative hospital stay of the remaining children was 4-8 (6.09 \pm 1.4) days. The total operation time of the small intercostal incision group was 24-72(47.54 \pm 12.06) min, of which the occluding time was 5-37(16.16 \pm 8.01) min, and the chest opening and closing time was 14-59(31.56 \pm 9.58) min. Pericardial effusion occurred in 2 cases after operation, the length of postoperative hospital stay was 13 days,23 days. The postoperative hospital stay of the remaining children was 3-9(5.79 \pm 1.45) days after operation. All cases were followed up for 2-30 months after the operation. They recovered smoothly without complications.

Compared with the small intercostal incision group, the sternal incision group had no statistically significant difference in operation time, occluding time, chest opening time, and postoperative hospital stay.

Discussion

Doubly committed subarterial ventricular septal defect, due to its proximity to the aortic valve and pulmonary valve, can easily lead to valve prolapse and regurgitation, and the self-healing rate is extremely low, so timely surgical treatment is required [9]. Traditional surgical treatment with cardiopulmonary bypass is definitely effective, but the surgical trauma is heavy. Incardiac catheterization interventional therapy, it is difficult to operate, and there are few reports. At the same time, it is exposed to radiation and the amount of radiation is large. Surgical esophageal ultrasound-guided interventional therapy provides new ideas for

minimally invasive treatment of DCS-VSD [10].

Originally, obvious aortic valve prolapse and reflux were contraindications for DCVSD occlusion by device technique, but we have different experience. Previously it was reported that even mild aortic prolapse can be associated with an occlusion failure, if a hybrid approach is performed[11,12,13]; in our series however, children even with a mild aortic prolapse received a successful transthoracic device closure, without further valve prolapse and valve regurgitation. Therefore, we guess that there is no general contraindication for device closure in case of a mild aortic valve prolapse or if preoperative evaluation shows a tear-drop prolapsed[14] or a mild aortic valve regurgitation.

According to the statistical data of this study, it is found that the small left intercostal incision for occluding DCS-VSD is no different from the lower sternal incision, but the intercostal incision does not need to cut the sternum, which avoids the occurrence of sternal hemorrhage and chicken breast, with less drainage after surgery. The surgical incision of intercostal about 1cm is smaller than the incision of the lower sternum which at least 2-5cm[Fig 7,8]. In addition, since the DCS-VSD is mostly located in the 2-3 intercostal space on the left margin of the sternum, after the TEE is positioned, the puncture sheath can enter almost perpendicular to the VSD, the puncture path is shorter, and it is easier to establish a delivery system compared to the incision of the lower sternum, so that it has more advantages. There are also reports about occluding DCS-VSD through the left underarm and right underarm. The surgical incision is at least 2-3cm, the average operation time is about 60min, and the intracardiac operation time is about 20min [6], both of which are longer than intercostal incisions. Of course, because the underarm incision has not been carried out in our hospital, there is no comparability of operation time and other data performed by different doctors, so it can only be used as a reference. But at least compared with the axillary approach, the small left intercostal incision has a small surgical incision, no need to open the intercostal space, less trauma, and also has more advantages.

In this study, there were 2 failure cases. One child was 11 months old and had a DCS-VSD, diameter of 6 mm. After using the No. 8 eccentric occluder, there was still a residual shunt of 2.5 mm, which was changed to cardiopulmonary bypass surgery. For residual shunts, general experience is that small shunts with a diameter of <1.5mm and a TEE measurement velocity of flow <2.5m/s can heal by themselves [15]. In this case, the residual shunt flow is large, there is low possibility of self-closing, and the child is too young. Enlarging the occluder size will affect the aortic valve function, so the final decision was to switch to cardiopulmonary bypass surgery during the operation. The other patient was 49 months old and had a DCS-VSD, diameter of 7 mm. During the operation, a No. 9 eccentric occluder was used. The occluder was displaced during the releasing of the occluder, and the operation was changed to cardiopulmonary bypass surgery. We consider that the residual shunt and occluder displacement have a certain relationship with the ultrasonic measurement method. In the case of slight aortic valve prolapse, because the prolapsed valve will cover part of the defect, measuring the size of the VSD according to the blood flow will often lead to a smaller measurement diameter, which leads to choose a smaller occluder, and caused residual shunt or displacement. Therefore, for patients with valvular prolapse, measuring the size of the defect should measure the distance from the defect to the root of the valve on a two-dimensional image, rather than simply measuring the size of Doppler blood flow. The experience of the ultrasound doctor is crucial to the operation. Good positioning can significantly shorten the operation time. Accurate measurement can reduce the occurrence of residual leakage and displacement. If a small intercostal incision is used but the cardiopulmonary bypass surgery is finally switched, there will be two surgical scars after the operation, which is contrary to the original intention of minimally invasive surgery. Therefore, for children with large DCS-VSD diameter, small age, and inaccurate defect measurement, it is still recommended to use the lower sternum incision. When the occlusion surgery is changed to cardiopulmonary bypass surgery, the operation can be completed by extending the original incision.

Conclusion

In summary, the small intercostal incision to occlude DCS-VSD is a safe, effective, small trauma, and cosmetic incision, and it is worth promoting as a conventional minimally invasive surgery for DCS-VSD.

We will also further increase the sample pool, improve postoperative long-term follow-up and other related work, and provide more comprehensive clinical data.

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