Trans-jugular Transcutaneous Closure of Atrial Septal Defects with an Adjustable Curved Sheath Under Echocardiography Guidance

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Abstract

Introduction and objectives: Traditional transcatheter closure of atrial septal defect (ASD) via the femoral vein carries risk of radiation damage. Transcutaneous closure of ASD under echocardiography guidance avoids radiation exposure and can be gradually applied. An alternative is to transcutaneous closure of ASD trans-jugular with an adjustable curved sheath under echocardiography guidance. **Methods:** We retrospectively studied all cases of trans-jugular transcutaneous closure of ASD with an adjustable curved sheath under echocardiography guidance in the Heart Center of Henan Province People's Hospital between 2016 and December 2022. **Results**: 156 patients were included, 74 males and 82 females. Mean age was 6.9 ± 7.4 years and weight 23.7 ± 14.6 kg. Mean sizes of the ASD and occluder were (9.7 ± 4.7) mm and (14.1 ± 5.7) mm. The mean operation time was (49.6 ± 29.2) min. No complications such as atrioventricular block, reoperation, or pericardial effusion occurred. There are 3 patients had a residual shunt. All patients were followed-up for (38.7 ± 11.0)months. The 3 patients with residual shunt had self-closed at the 3-6-12months follow-up. There was no complication at follow-up. **Conclusion:** Trans-jugular transcutaneous closure of ASD with adjustable curved sheath under echocardiography guidance is safe, effective and minimally invasive.

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Running title: Trans-jugular Closure Atrial Septal Defect

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Key words: Atrial Septal Defect (ASD), Adjustable Curved Sheath, Transcutaneous, Echocardiography guidance

Text

Abbreviation: ASD: atrial septal defect, ICU: intensive care unit, TEE: transesophageal echocardiography M+-SD: mean +- standard deviation

Introduction

ASD is one of the most common congenital heart diseases, accounting for about 10-20% of all congenital heart diseases[(1)]. Traditional treatments—surgical extracorporeal circulation operation and transcatheter intervention therapy—have advantages and disadvantages. Transcatheter interventional therapy causes minor trauma and provides rapid recovery, but the use of radiation can damage the function of bone marrow, genitals, thyroid and other organs, and the use of contrast medium has a risk of an allergic reaction or renal insufficiency [(2,3)]. The surgical extracorporeal circulation operation method is mature and has more indications, but it needs extracorporeal circulation, causes major trauma and unsightly incision. In recent years, echocardiography guided transcutaneous closure of ASD has gradually been applied. At present, the most common approach for transcutaneous ASD occlusion under the guidance of echocardiography is through femoral vein [(4-9)]. However, this approach requires a relatively long operation path and the patient requires a long period of bedrest after femoral vein puncture. The femoral vein is slender in young patients, which limits the application of this technique. An alternative is to use the larger dimeter jugular vein, increasing the suitability in younger children[(10-12)]. This approach also has shorter operation path and so requires shorter delivery system [(11)]. Recent reports have highlighted the safe and effective use of trans-jugular ultrasound-guided closure of ASD [(10-12)]. The use of an adjustable curved sheath for transcutaneous occlusion by this approach means the head of the sheath can be bent $0\text{-}90^0$, easing entry to left atrium through ASD under the guidance of transesophageal echocardiography (TEE). Though trans-jugular transcutaneous closure of ASD with an adjustable curved sheath under echocardiography guidance is few reports. Since 2016, the Heart Center of Henan Province People's Hospital has started to use an adjustable bent sheath to close ASD under echocardiography guidance. The patients have been followed-up regularly, and the procedure has achieved good results.

We report the safety and effectiveness of this method to provide more information on this approach for clinicians interested in adopting the method in suitable patients.

Methods

Patients : We retrospectively studied 156 cases (74 males and 82 females) who underwent trans-jugular transcutaneous closure of ASD with an adjustable curved sheath under echocardiography guidance in the Heart Center of Henan Province People's Hospital from January 2016 to December 2022. All patients were diagnosed with ASD by echocardiography. According to the guidelines for interventional treatment of congenital heart disease[13] . The inclusion criteria were as follows: 1) secundum ASD; 2) increased right ventricular volume load; 3) left-to-right shunt; 4) in addition to the absence or insufficiency of the stump margin of atrial septum on the aortic side, the stump margin of the superior and inferior vena cava, the stump margin opposite the aortic root, and the stump margin of the mitral valve annulus should be [?] 3 mm; 5) the maximum extension diameter of the atrial septum was larger than the left atrial surface diameter of the selected occluder. The exclusion criteria were as follows:1) primum ASD; 2)Severe pulmonary hypertension; 3)age $<$ 6 months; 4)the stump margin of the superior and inferior vena cava, the stump margin opposite the aortic root, and the stump margin of the mitral valve annulus should be $<$ 3 mm

All patient and family members were informed and agreed to performance of this operation.

Intraoperative TEE was performed using GE Vivid EQ5 portable ultrasonography (GE Healthcare Biosciences, Piscataway, NJ, USA). The occluders and adjustable bent sheaths were produced by Shenzhen LifeTech Scientific Corporation China. The conveying device included loading sheaths and push cables (Figure 1).

Operative Procedure

All surgeons with more than 5 years of experience. According to the edge length and toughness of the ASD, an occluder that was 2–6 mm larger than the ASD diameter was selected. Heparin 1 mg/kg was routinely administered before the operation with no postoperative protamine neutralization. Routine postoperative with aspirin (3–5 mg/kg) for 6 months.

The ASD diameter and atrial septum length were measured in several views (four-chamber view, parasternal short axis and double chamber section) by TEE. The distance from the puncture point to the third intercostal on the right side was measured, which was marked as the working distance. The right internal jugular vein was punctured with a 16G puncture needle using echo-guided, and the guidewire was placed through the puncture needle into the right atrium (about working distance length), the puncture needle was removed when the guidewire reached the superior vena cava edge of the ASD through TEE inspection, and the guidewire was kept in the right atrium. An adjustable bent sheath (Shenzhen LifeTech Scientifc Corporation) was prepared, which was able to adjust the head curvature from 0 to 90^0 for ASD. (Figure 1) The adjustable curved sheath (with inner core) entered the right atrium through the jugular vein along the guidewire. When the length reached the working distance, the guidewire and inner core were removed. Under the guidance of TEE, the sheath slowly entered the middle of the ASD parallel to the atrial septum. The manipulator was gently rotated clockwise to gradually bend the head of the sheath make the sheath passed through the ASD to the left atrium. The occluder with cable was delivered into the left atrium though sheath with the help of TEE detector.

The left side was released first, the cable was then pulled back to release the right side. TEE was used to observe the occlude position. This included whether it straddled the atrial septum, was parallel to the atrial septum, encircled the aortic root, and the residual edge of the atrial septum was located between the two plates. Also, whether there was residual shunt, whether the occluder affected the activity of the mitral valve, tricuspid valve, whether the occluder affected the return of the pulmonary vein and the superior and inferior vena cava. The occluder was released after a push-and-pull test if there was no residual shunting, no effect on surrounding tissue, and no arrhythmia. The manipulator was rotated to straighten the head of the adjustable bent sheath, the sheath was pulled out, and pressure was applied to the puncture point which

was then bandaged. (Operative Procedure see Figure 2). The tracheal tube was removed in the operating room or intensive care unit (ICU), and all patients returned to the general ward after extubation.

Follow up

Follow-up was organized for all patients with clinical, electrocardiogram (ECG), and echocardiographic assessment. Complications, such as atrioventricular block, pericardial effusion, thromboembolism, hematoma at puncture, before discharge, 1 month, 3 months, 6 months, and 12 months after the procedure were recorded.

Statistical Analysis:

SPSS21.0 software (IBM, Inc., Armonk, NY, USA) was used for statistical analyses. The data were in normal distribution. The measurement data are represented as means +- standard deviation and were analyzed using the independent t-test. The enumeration data are represented as frequency (percentage) and were analyzed using the X2 test.

Results

Patient characteristics

In total 156 patients were included, 74 males and 82 females. The mean age was 6.9 +- 7.4 years and mean weight was 23.7 +- 14.6 kg. There were 114 cases with different levels of tricuspid regurgitation. The baseline characteristics and perioperative information are shown in Table 1.

Perioperative results

The mean size of the ASD was 9.7 +- 4.7 mm, and the occluder was 14.1 +- 5.7 mm. The mean length of the superior vena cava rim, inferior vena cava rim, aortic rim, posterior rim and atrioventricular valve rim were 8.5 +- 4.0 mm, 11.4 +- 4.3mm, 1.8 +- 2.2 mm, 9.3 +- 3.4 mm, and 9.1 +- 3.2 mm. Tricuspid regurgitation was 1.1 +- 1.0 cm^2 and mean pulmonary artery pressure was 30.9 +- 9.4 mmHg. The type of bent sheath was 8.3 +- 1.6 F. The operation time(From puncture right internal jugular vein to leaving the operating room) was 49.6 +- 29.2 min, the ICU time was 6.9 +- 8.3 h, the ventilator time was 1.2 +- 1.5 h. No case required blood transfusion. All patients were occluded successfully. There are 3 patient had a small residual shunt of 1-2mm. The residual shunt had disappeared at the 3-6-12month follow-up. There were no complications such as atrioventricular block, pericardial effusion, thromboembolism, hematoma at puncture site and arteriovenous fistula.

Follow-up results

The patients were followed up for 38.7+-11.0 months. No complications (e.g., reoperation, atrioventricular block, occluder abscission, thromboembolism) were observed.

Discussion

ASD is a common type of congenital heart defect in children and careful selection of treatment is important for those who are unlikely to self-heal. The aim of this study was to retrospectively analyze the safety and effectiveness of trans-jugular transcutaneous closure of ASD with an adjustable curved sheath under echocardiography guidance. We, therefore, present the clinical data from 156 patients treated in our department. The procedure was effective and safety.The first cases of transcatheter closure ASD were described in1974 [(14)]. The traditional transcatheter treatment had little trauma, the patients recovered quickly, they could get out of bed as soon as possible, return to work, with short hospitalization time. This saved time and economic cost; there was no surgical incision, a good cosmetic effect; no bleeding, and complications related to blood transfusion were avoided. Houeijeh reported their study of transcatheter closure of large ASD in symptomatic children [(15)]. This method has become preferred for the treatment of secondary ASD [(16,17)]. However, there are some risks with the use of radiation and contrast media may cause allergy and renal insufficiency [(2,3)]. Most of these treatments also need use expensive catheterization room or hybrid operating room. In recent years, the use of echocardiography instead of radiation for interventional therapy has

become an important method. Ewert showed that transcutaneous ASD occlusion guided by TEE alone was feasible [(4)]. Schubert reported 1605 cases of transcutaneous ASD occlusion, which showed that TEE guided transcutaneous ASD occlusion can achieve the same safety and effectiveness as a radiation-guided method [(5)]. Seol[(6)], Sharfi[(7)], Lu[(8)], Snijder[(9)], and Zhang[(12)], have all reported transcutaneous close ASD under echocardiography guidance. At present, transcutaneous ASD occlusion under echocardiography guidance is commonly through the femoral vein [(4-9)]. But this method has a long operation path and needs long bedrest after femoral vein puncture.

We transcutaneous closure of ASD with an adjustable curved sheath under echocardiography guidance though jugular vein which no need femoral vein puncture or lower-limb braking. It has been suggested that this method can reduce bedrest and significantly increase patient comfort[(10, 11)]. It may also reduce the risk of vein thrombosis, and bleeding of puncture point may reduce because of a relative decrease of jugular venous pressure after the operation. All 156 patients in this study had no bleeding at the point of puncture. Especially for infants, the diameter of the jugular vein is larger than that of the femoral vein [(18)]. Transcutaneous interventional therapy via the jugular vein can relax the restrictions of the vascular conditions on the type of the transport sheath, which makes it possible to treat young patients with relatively large ASD.

The operation time(From puncture right internal jugular vein to leaving the operating room)was 46.6 +-30.9 min in this study, The intracardiac operation time is significantly less. A comparative analysis of the duration of the procedure from when the operators started to use it versus when they were considered experiente, could show differences. The operation time of 56 patients in the first two years was 60.7 +-37.6 min, and The operation time of the next 100 cases was significantly reduced 43.6 +-21.3 min($P<0.01$)

, and a range of 25 to 30 minutes[(10.11)] in other studies that used a similar approach. So, this method has a relatively short operation time when compared to transcutaneous ASD occlusion under the guidance of echocardiography through the femoral vein which Shubert showed had a median procedure time of 50 min with a range of 20-170 min[(5)]. The safety of the method was shown by no complications occurring during the procedure of during follow-up. This was also similar to previous studies with similar methods[(10, 11)].

Our experience of trans-jugular transcutaneous closure of ASD with adjustable curved sheath under echocardiography yielded the following conclusions

1. The preoperative ultrasound diagnosis is clear, and the cooperation of experienced ultrasound doctors is important. During the operation, multiple sections of TEE are needed to evaluate the ASD size and each edge situation. The operator needs to have certain ultrasound knowledge, if the defect edge is tough, even if only 3mm closure can be tried; the operation is easier under the guidance of a double chamber view. The movement of the adjustable sheath into the left atrium should be gentle to avoid damaging left atrium.

2. Select the appropriate occlude. We choose to use a double chamber view, four chamber view and aortic short axis view to measure the maximum diameter of the ASD, and take the average value as the ASD size. We then added 2-6mm to the find the correct occluder size, if the edge was tough, we chose a relatively small occluder, if the quality was soft, we chose a relatively large occluder.

3. After the right disk of the occluder is released, due to a certain angle traction at the head of the transport sheath, TEE shows the occluder may be unnatural in shape; at this time, multiple views are needed to check if the atrioventricular valve rim, inferior vena cava rim, superior vena cava rim, posterior rim and aortic rim are "stuck" between the left and right disk of the occluder, the occluder can be released. In general, the shape will become very natural after the occluder is released.

4. The operation needs a team of doctors with experience in minimally invasive procedures. If transcutaneous closure is unsuccessful, it can then be directly changed to transthoracic minimally invasive closure or cardiopulmonary bypass close ASD.

Our study has some limitations. The retrospective analysis method is likely to have patient selection bias. More studies that directly compare this method with other methods are needed to confirm that this method

can be recommended.

Conclusion

Trans-jugular transcutaneous closure of ASD with an adjustable curved sheath under echocardiography guidance is safely, effective and minimally invasive. With the development of science and technology and research into the application of a degradable occluder[(19)], its application will be more extensive.

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Figure legend

Figure 1. Images of the device used to perform atrial septal defect closure.

A:The conveying device includes loading sheaths, push cables, adjustable bent sheath and inner core.

B:The adjustable bent sheath can adjust the head curvature from 0 to 90^0

Figure 2.Operative procedure images.

A: The central ASD.

B: The guidewire is placed through the superior venacava into the right atrium.

C and D:The adjustable curved sheath enters the right atrium through the guidewire, the manipulator is rotated and gently rotates the sheath. The sheath passes through the ASD to the left atrium.

E and F:A steel cable is used to feed the occluder along the sheath,and the occluder is delivered into the left atrium and the left side is released.

G: push-and-pull test.

H: The occluder is released.

ASD: atrial septal defect.

IRB information: The study was approved by the Medical Ethics Committee of the Henan Provinces of People's Hospital.

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