Summary of Experiences & Result of Transesophageal Ultrasound Guided Ventricular Septal Defect and Atrial Septal Defect Closure Operation

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Abstract

Objective: Analysis conducted by using Transophageal Echocardiography to monitor the therapeutic effect of closure of Ventricular Septal Defect and Atrial Septal Defect.**Method:** The clinical data of 928 patients for closure operation of transthoracic, percutaneous Ventricular Septal Defect (VSD) and Atrial Septal Defect (ASD) guided by transesophageal ultrasound was retrospectively analyzed for the Department of Cardiac Macrovascular Surgery, the First Affiliated Hospital of Nanchang University between August,2009 and August, 2019 .There were 552 cases of VSD and 376 cases of ASD and 478 males and 450 females, with age distribution ranging from 4 months to 74 (8.64±2.42) years old, and body mass distribution ranging from 8 to 56 (23.32±12.26) kg.**Result:**Closure operation conducted turned out a successful one for the whole group of patients without any casualty cases and a tally of 907 were successful (97.7%.Out of 552

VSD patient in the group 540 were treated successfully with the transthoracic closure approach and 12 cases required extracorporeal circulation after failure of the transthoracic approach. Among the 256 cases, the patients with ASD was treated by transthoracic closure approach, 251 successful cases , 2 cases failed and 3 shedding cases. Besides, 120 percutaneous closure cases is carried out with 116 successful cases,2 failing cases and 2 shedding cases. Post-operation follow-up was conducted for the patients with successful closure operations,which demonstrated that complications of aortic and tricuspid regurgitation, hydro-pericardium,IIIºatrioventricular block, shedding of closure umbrella, hemolysis and thrombus had not occured. Intraoperative blood loss was 15ml-35ml (23.64±4.26), postoperative ventilator using time was 2h-10h(4.76±0.33), and hospital stay was 4d-10d(6.43±1.26). **Conclusion :** Ventricular septal defect (VSD) and atrial septal defect (ASD) closure operation by esophageal ultrasound is endowed with the advantages of less trauma, less blood loss, shorter hospital stay, simple operation, fewer postoperative complications and significant therapeutic effect.

Key words: Congenital heart disease; Transesophageal Echocardiography (TEE); Minimally Invasive; Transcatheter Closure.

Introduction Ventricular Septal Defect (VSD) is a clinically common congenital heart disease with the morbidity accounting for 20-25% of all congenital heart diseases [1-4].Atrial Septal Defect (ASD) is one of the most common congenital heart diseases, constituting about 30% of congenital heart disease [5]. Extracorporal circulaton by Heart Septal Defect ventricular generally uses traditional surgical treatment about ASD and VSD.Although percutaneous catheterization closure operation by X-ray of Internal Medicine Department is considered as one of the effective treatment methods for VSD and ASD, considering that X-ray has certain damage to patients [6-7], thoracotomy will be required if failure of closure occurs , which is difficult for cardiologists to achieve, thus narrowing the clinical application of percutaneous interventional therapy.Over the years,transesophageal ultrasound has gained the favour of the majority of clinicians and patients with the unique advantages over others,transthoracic,percutaneous Ventricular Septal Defect and Atrial Septal Defect closure operations.The surgical minimally invasive VSD and ASD closure operations, since its inceptive application into clinical treatment and through persistent technical improvement, are becoming increasingly mature.Currently ,the clinical data of patients for VSD and ASD Closure Operations guided by esophageal ultrasound by Department of Cardiac Macrovascular Surgery, the First Affiliated Hospital of Nanchang University between August,2009 and August, 2019 is ready for retrospective analysis.

1 Date and Approach

1.1General Data

Among the 928 patients, 478 cases are males (51.5%) and 450 female cases (48.5%), aging varies from 4 months ~74 (8.64±2.42) years old, with body mass of 8-56 (23.32±12.26) kg and 552 cases of VSD（59.5%）and 376 cases of ASD（40.5%）they were diagnosed by transthoracic and echocardiography (TTE),chest X-ray and electrocardiogram as the last diagnosis .By chest X-ray analysis ,75 patients were diagnosed with pulmonary congestion and pulmonary hypertension .

The pre-operation TTE examination revealed that 552 patients suffer VSD, 487 patients with perimembranous defect which includes 179 patients with septal tumor , 10 cases of MVSD and 55 cases of DCSA VSD with defect diameter of 2~11mm（5.35±1.25).In 376 cases of ASD, 323 cases are of central type (oval-shaped) ASD, 53 cases belong to inferior vena cava(IVC) of ASD with defect diameter of 3~36mm（17.52±4.27）.See Table 1 for specific data.

Table 1. General information of patients with congenital heart disease

Group	Case (n)	Gender (case，male/ female)	Age (years)	Weight (kg)
VSD	552	268/284	7.02 ± 2.36	22.62 ± 11.23
ASD	376	210/166	9.36 ± 2.52	24.45 ± 13.35

1.2 Inclusion & Exclusion Criteria

Inclusion criteria: （1）No Contradiction by preoperative blood biochemical examination;

（2）The VSD and ASD were diagnosed with TTE without other Inter cardiac malformations;

（3）The defect does not involve the cardiac valves and is not accompanied by moderate or above valvular regurgitation.

Exclusion criteria: （1）Infectious disease within 2 weeks before surgery ;（2）Mural thrombus was found in the heart cavity.; (3) Hemolytic disease or coagulation dysfunction; （4）Patients with severe pulmonary hypertension or Eisenmenger Syndrome; （5）Patients with decompensated heart failure and left ventricular ejection fraction <30%.

1.3 Ways of Operation

General anesthesia, endotracheal intubation were adopted.In order to assess the defect location,size,marginal conditions, and adjacent valve activity TEE probe was slowly placed in the oesophagus.

BY transthoracic closure:①A median incision of 1.5 - 2 cm was taken from the lower sternum running to the upper sternum via a dissection with an electric saw;②The pericardium was cut open and suspended, and 1mg/kg heparin was injected intravenously;③Esophagus ultrasound was used to locate defect puncture point on the heart surface;④Double needle with gasket and preset purse on the surface of the heart, puncture with trocar;⑤Place the guide wire through the defect⑥ Place the sheath canal along the guide wire and remove the sheath core.⑦Select the corresponding size of the blocking device in turn release left, right umbrella.⑧After the closure device was released completely, the surrounding valve was observed by ultrasound to see whether there was any movement obstacle or defect residual shunt;⑨Conveniently withdraw and remove the stee wire and observe if the closure device clamps firmly.⑩Exit wire and sheath tube.

Tighten the purse and tie a knot in the heart surface after successful transthoracic closure, carefully prevent blooding and close part of pericardium , after indwelling drainage tube, close the chest;

Percutaneous closure approach:①Femoral vein puncture and place 6F femoral sheath;②A 6F single-curved catheter and a hard guide wire were inserted through the vagina vasorum;③Rotating catheter forced through the defect region guided by echocardiography and a ridgid guide wire tuck in the left pulmonary vein;④Retaining the guide wire and exchanging the corresponding closure device for conveying sheath canal;⑤Regarding closures diameter device depicted,select7-18F delivery sheath;⑥Follow the guide wire into the left atrium and remove the sheath core;the following steps are basically consistent with the transthoracic approach.

Patients with the percutaneous closure, the puncture point should be pressed for more than 15min to stop bleeding, and the elastic bandage should be pressurized and wrapped for 4-6h.

All patients were asked to orally take 3-6 months of aspirin of 3-5mg /kg after surgery, and echocardiography and electrocardiogram were reexamined after one month, three months and six months after surgery and annually.

1.4 Observation Index

A total of 907 patients with successful closure were re-examined at 1 month, 3 months, 6 months and 12 months respectively after surgery by cardiac color ultrasound to see whether there was residual shunt or cardiac valve activity disorder.The ECG was reviewed so as to determine whether there was symptom of atrioventricular conductional block.Telephone follow-up was conducted for patients over 2 years after the operation at intervals of 3, 5 and 10 years after the operation, and growth status, activity ability and related secondary surgery or other complications were recorded.

1.5 Statistical Analysis

SPSS22.0 statistical software was used to analyze the data, and the measurement data was expressed as (mean±S.D.), t-test was used for inter-group comparison, and the enumeration data was expressed as example (percentage), Chi-square test was used for inter-group comparison, and $P < 0.05$ was statistically significant.

2 Results

2.1Operation Results

907 cases turn out to be successful closure (97.7%) with the group not recording any death casualties by operation and related actions. The operation results were divided into three categories according to whether the operation was successful or not, that is , successful closure, difficult closure, failing closure. Successful closure means that the puncture point is accurate, the guide wire and sheath canal pass smoothly, and the closure device is firmly clipped. Difficult closure was regarded as a reminder that it is difficult for the guide wire and sheath canal to pass through the defect or the closure device is not in line with the diameter of the defect. Therefore, it is necessary to adjust the puncture point or replace the closure device to complete the closure. Failing closure means that the closure device cannot be attached or is forced to abandon due to valve dysfunction and atrioventricular block after implantation. There were 552 cases with VSD

closure and 540 out of 552 were successful with success rate of 97.8%. Similarly, 376 cases with ASD closure, among which 367 cases successful, the success rate was 97.6%. See table 2.

Table 2 Results of minimally invasive closure surgery in VSD and ASD (Cases)

Group	Successful Closure	Failing Closure	Shedding Closure	Success Rate
VSD	540	12	-	97.8%
ASD	367	4	5	97.6%

552 patients with VSD choose transthoracic small incision closure and 3 cases with closure difficulty and was mainly caused by membranous tumor with multiple outlets and the inlet diameter is > 10mm with DCSA VSD and MVSD as the major forms. The size and defect plays a key role to the successful closure of VSD.Moreover,the 179 closure cases were diagnosed via thoracic approach to contain membrane tumour VSD,12 other with closure difficulties,7 with chest opening and repair after breakdown of closure, 10 with MVSD, among which 4 have closure difficulties,2 breakdown situations, 55 with DCSA VSD and 6 with closure arduousness ,2 with thoracotomy mend after breakdown closure, see table 3.

Table 3 Results of VSD closure (Cases)

	Type and diameter of VSD									
Group	Peripheral VSD	MVSA Single outlet	MVSA Multi-outlet	MVSA Multi-outlet	Muscular VSD	SPVSD	P1	P2	P3	P4

		Inlet Diameter≤10mm		Inlet diameter≤10mm	ID > 10mm				
	(n=308)	(n=68)	(n=90)	(n=21)	(n=10)	(n=55)			
Smooth closure	297	65	83	12	4	47	0.596	<0.001	<0.001	0.101
Closure Difficulty	10	3	5	4	4	6	1.0	0.087	0.002	0.304
Failing closure	1	-	2	5	2	2	0.507	<0.001	<0.015	0.198

P1 is the comparison between a single outlet with inlet diameter ≤10 mm and multi-outlet with inlet diameter ≤10 mm for membrane tumor. P2 is the comparison of single outlet diameter ≤10 mm with multi-outlet and inlet diameter >10 mm for membrane tumor. P3 is the comparison of single outlet of membranous tumor and inlet diameter ≤10 mm with muscle defect. P4 was the comparison of membrane tumor with a single outlet and inlet diameter ≤10 mm with lower dry defect.

All 376 cases of ASD in the whole group were secondary hole type. According to the defect site, they were divided into four types: central type (oval hole type), inferior vena cava type, superior vena cava type and mixed type. The central type was the most common type, accounting for 75%.In this group, only central and inferior vena cava defects were seen.See table 4.

Table 4 Statistics of Atrial Septum Types and Closure Pathways (Cases)

Group	Transthoracic Closure	Percutaneous closure	Total
Central type (oval hole)	223	100	323
Inferior vena cava	33	20	53
Total	256	120	376

Among the 376 ASD cases, 24 cases were in closure difficulty and 4 cases failed, including 2 cases failed with percutaneous closure. Due to the fact that the defect diameter is more than 30mm, After implantation of the large closure device, the pressure conduction bundle was pressurized combined with valve movement disorder, and direct repair was performed under extracorporeal circulation.There were 2 cases of percutaneous closures ASD, and the closure device was not tightly clipped due to poor defect edge conditions and shed within 3 days after operation.The cases of failure of percutaneous closure were concentrated in ASD with defect diameter ≥30mm.See table 5.

Table 5 Influence of ASD defect diameter on percutaneous closure results (Cases)

Group	Defect diameter of ASD patients						
	≤5mm (n=35)	**＞5mm~≤20mm (n=45)**	**＞20mm~≤35mm (n=26)**	**＞35mm (n=14)**	**P1**	**P2**	**P3**
Smooth closure	34	41	20	7	**0.522**	**0.193**	**0.002**
Difficult closure	1	4	4	5	**0.522**	**0.657**	**0.044**
Failing closure	-	-	2	2	**-**	**0.131**	**0.053**

P1 is the comparison between 5mm~20mm and ≤ 5mm. P2 is the comparison between 5mm~20mm and 20mm~35mm.P3 is the comparison between 5mm~20mm and > 35mm.

Transthoracic closure was chosen by 256 cases of ASD, of which 10 had closure hardship,2 had closure failure and turn to extracorporeal round flow thoractomy mending,which qualities are all lesser than vena cava, Because of its defect diameter was more than 25mm, which was relatively large compared with the central defect, the lower edge was completely missing or only had a little residual thin-film tissue, so the whole defect was connected with the inlet of the inferior vena cava into the right atrium, which made the closure device unable to clamp the defect edge and thus caused the closure failure.In addition, there were 3 cases of central type ASD with the defect diameter exceeding 25mm, which also resulted in the loss of the closure device after surgery due to the poor edge conditions of the defect.As shown in table 6.

Table 6 Influence of ASD defect diameter on transthoracic closure results (Cases)

Group	Defect diameter of ASD patients							
	≤10mm (n=86)	**＞10mm~≤15mm (n=55)**	**＞15mm~≤20mm (n=72)**	**＞20mm~≤25mm (n=25)**	**＞25mm (n=18)**	**P1**	**P2**	**P3**

Smooth closure	86	54	71	22	8	1.0	0.086	<0.001
Difficult closure	-	1	1	3	5	1.0	0.086	<0.001
Failing closure	-	-	-	-	5	-	-	<0.001

P1 is the comparison between 16mm ~ 20mm and 11mm ~ 15mm. P2 is the comparison between 16mm ~ 20mm and 21mm ~ 25mm. P3 is the comparison between 16mm ~ 20mm and > 25mm.

Data illustrates that there were 308 situation of Peripheral ventricular Septal defect(VSD) of which 552 situation of VSD and 10 other situation of muscle-bound VSD. All VSD operations were conducted via thoracic approach with the maximum diameter of the closure of 10mm. 12 situation were of unsuccessful closure and turn to the extracorporeal distribution thoractomy, which were sequentially 5 situation of membrane tumor defect of VSD with diameter of <_10mm with multiples outlets.2 patient with DCSA VSD were unsuccessfully attached with the closure device as the edge is narrow and short. Besides, there 2 situation of muscular VSD and 1 case of peripheral ventricular septal defect(VSD) and as for its unique location, as the result, the guide wire failed to pass through.

Among the 376 cases of ASD, 116 successful cases of percutaneous closure with defect diameter mainly concentrated on the range of 3mm~20mm. There were 251 successful cases of transthoracic closure with defect diameter mainly distribution spanning from 5mm~25mm. Besides, there were 4 cases of chest opening and repair after failure of closure, which included 2 cases with defect diameter ≥30mm, and the valve opening and close were influenced and conduntion bundle was pressurized after the closure device was placed, as a result, thoracotomy repair was adopted. In addition, two failed cased as for the inferior vena edge was completely missing. 5 cases with shedding closure devices occurred for various reasons.

The surgery method can be sectioned into 2 parts ,that is through the transthoracic and

Percutaneous method as VSD and ASD closure surgery were performed by transophageal ultrasound. And different approaches can be chosen according to defect type and the size of diameter. See table 7.

Table 7. Effects of different approaches on closure effect (Cases)

	Thoracic approach			Percutaneous approach		
Group	Success	Failure	Shed	Success	Failure	Shed
VSD	540	12	-	-	-	-
ASD	251	2	3	116	2	2
TOTAL	791	14	3	116	2	2

2.2 Follow-up result

Patients were followed up at regular interval at one month, three months , six months, 12 months, three years ,five years and ten years after operation through postoperative outpatient reexamination and telephone review. 845 patients out of total 928 were followed up with a follow-up rate of 91.1% and the majority of patients were found out of contact. There were 5 cases with shedding closure device which included 3 cases via thoracic ASD approach and 2 cases via percutaneous ASD approach. Shedding of closure device was not found after VSD closure operation.

3 Discussion

Presently the therapy pattern for inborn heart sickness generally include old fashion open operations ,percutaneous Catheter intervention , all sorts of types of negligibly intrusive operations with little cut, shootings-assisted thoracoscopic operations and machine-assisted operations.Although traditional surgical repair is independent of patient age, body mass, diameter and location of the defect, it has a definite advantage especially for patients with young age, low body mass and pulmonary hypertension, or even the failure of interventional therapy.However, these methods have their drawbacks more or less. For example, central thoracotomy and extracorporeal circulation in traditional surgery will cause great trauma to the body, accompanied by high intraoperative blood loss, slow postoperative recovery, unaesthetic incision healing and great influence on postoperative respiratory function in high-risk patients.Long hours of video-assisted thoracoscopic and robot-assisted systems are required to master and learn complex operations. Percutaneous catheterization is required to be performed under the guidance of X-ray angiography, which to some extent causes damage to patients and medical staff. Once the closure fails, it is difficult for cardiologists to apply for cardiopulmonary bypass thoracotomy repair ,which narrowed the clinical indications of the above treatment methods for congenital heart disease [8,21].Negligible engaging operation closure,operations unifies the benefits of open vision mend under extracoporeal distribution and Precutaneous Catheter intervention , displaying the benefits of quickness, agreeable,malleability,surgery adaptability and enhances mutual surgery and internal medicine. At the same time, it can reduce surgical risk and trauma, avoid X-ray and catheter intervention injury, improve surgical efficacy and reduce various complications [22,27].The operation has two kinds of routes: transthoracic and percutaneous approaches.Transthoracic closure approach is endowed with the advantage of short path, wide indications, no special requirements for the patient age and esophagus ultrasonic was used for all procedure evaluation for valves activity disorder and III atrioventricular block after the closure device was implanted in, and as closure failure occurred and closure device shed, we can turn to thoracotomy immediately and as a priority for ASD or VSD. The percutaneous closure, with no intraoperative X-ray, no pollution, more minimally invasive and surgical support, is frequently applied in pediatric ASD.

According to the embryonic development there are many types of VSD which are generally divived into three types namely : perimembrane, funnel(intercristal VSD and DCSA VSD) and muscular VSD. Perimembrane was the most commonly seen, with 487 cases of perimembrane VSD including 179 cases of neoplasia in membranous part.There are 540 successful cases of VSD closure ,Which all took thoracic approach , with success rate of 97.8%, 12 cases failure: mainly concentrated on DCSA VSD, muscular VSD and MVSA with multi-outlets and inlet diameter > 10 mm diameter, and the difficulty of the closure of single perimembrane for the patients compared with that of patients with pure peripheral ventricular septal defect(VSD), single outlet of membrane tumor with defect diameter≤10mm was statistically differentiated.

The defect is located in the rear lower area of opening area of ventricular outflow tract , aorta and pulmonary artery,which adds difficulty for DCSA VSD closure. Intuitively, part of the pulmonary valve ring and part of the aortic valve ring constitute the upper edge of the defect. If the defect is large in diameter, the anterior part of the right coronary valve can be seen through the defect, leading to intraoperative injury of the aortic valve.According to experience, a special high and low partial heart-shaped closure device was selected for the closure of the DCSA VSD with remarkable effect. The closure of DCSA VSD requires accurate measurement of anatomical defects, and the high and low eccentric closure umbrella was selected to reduce the influence of the closure umbrella edge on the conduction beam.Because of its small left ventricular surface, there is no possibility of affecting the opening and closing of aortic valve.

VSD membranous tumour is distinguish by huge base diameter,narrow wall,numerous incision and feeble environment tissue of the incision,increase level of hardship for closure,so preoperative assessment and the choice of interaoperative closure tools must be rightly set.

According to the experience, the success rate of patients with VSD preoperative auscultation evaluation, loud auscultation area noise, limited scope is higher. For the selection of closure device model, VSD defect diameter + (1-2mm) and ASD defect diameter + (4-6mm) were adopted. Compared with the transthoracic VSD closure, the percutaneous approach showed such defects as long path, poor hand feel, poor controllability and difficulty in pre-expansion.Transthoracic closure route includes three ways: through 1/3 median lower of the sternum, through left parasternum and through right atrium. The first way was the most widely used in clinical practice.According to different types of VSD, the corresponding surgical pathways can achieve satisfactory clinical results.

The location and size of ASD vary greatly, with the most common diameter ranging from 15 to 30mm. However, from the perspective of clinical imageology,the missing area varies from 10mm to almost the whole atrial septum.There were records in the literature that ASD patients with defect diameter <8mm have the possibility of self-closure [28,29], but the possibility of self-healing after 5 years old was very small.ASD in this group was secondary hole type, which was divided into central type (oval hole type), inferior vena cava type, superior vena cava type and mixed type according to the defect site.The most common type is the central type, followed by the inferior vena cava type.

The history of ASD treatment currently takes the forms of operations can be traced back in the 1960’s. It is reported that the interventional treatment of ASD has made significant progress in the past few years. Compared with other surgical methods, this method has advantages of short hospital stay and fewer complications [30].In recent years, with the development of minimally invasive technology, minimally invasive surgical closure operation has been widely carried out clinically [31,32].Operations by transthoracic and percutaneous approaches can also be adopted for ASD closure guided by esophageal ultrasound.

ASD with small diameter by percutaneous closure (defect diameter _< 5mm) and ASD with defiance diameter _<10mm through transthoracic closure was100% successful respectively in congruence to the examination of successful closure of 367 ASD patient in the group. ASD with small diameter is mainly of the central type, and the guide wire and sheath canal will be blocked by secondary septum in transthoracic closure, which will lead to the difficulty or even failure of closure.Because the direction of guide wire and sheath canal is just opposite to the opening of the defect Percutaneous closure becomes easier to succeed. For ASD with defect diameter of > 5mm~≤20mm, both approaches were available, with no statistical difference in the success rate, but the percutaneous closure was more minimally invasive.In particular, it is particularly important to adjust the release Angle of the closure device during ASD percutaneous closure operation.So as to achieve the best surgical result the Catheter should be inserted into the left upper pulmonary ven via the leading wire in order for the release angle of the closure device looks at right angle to the defiance plane. Meanwhile, it is necessary to guard against the rupture of the guide wire caused by violence into the left cardiac ear.ASD with defect diameter of > 20mm~ 35mm were better treat it by esophageal ultrasound-guided transthoracic closure, and the difference was statistically significant (P<0.05)Resulting in difficulty in vascular dilation and inability of the leading cable and sheath canal in patient be at right angle to the defiance plane the rate of intraoperative umbrella and replacement, the difficulty of closure and the probability of mishap of percutaneous closure is seldom used. For ASD with a defect diameter of > 35mm and good defect edge conditions, a short operation path and a good release angle of the closure device are generally selected.Even so, the difficulty of closure and the possibility of failure were significantly higher than that of ASD patients with defect diameter ≤35mm ($P<0.05$), and the closure device was likely to fall off after surgery.

Five situation of closure device dropping off in the group of patient after ASD surgery and two situation of closure device dropping off for defiance diameter >35mm after surgery. In addition, 3 cases of inferior cavity defect fell off on the 3rd day after the operation due to poor marginal conditions and poor clamping of the closure device. All the 5 patients received thoracotomy with closure device picked out and cardiac defect repair operation under direct vision, and the patients were in good condition in postoperative review.Therefore, if the ASD diameter>35mm , the closure should be avoided as much as possible, reasons were enumerated as follows: (1)large defect is easy to lead to increase of error of the defect diameter evaluation, resulting in increased intraoperative umbrella rate, thus extending the operation time and increasing the patient trauma; (2) Large defect is more likely to cause irregular, incomplete or short and thin defect edge, resulting in loose closure device, increasing the possibility of shedding;(3)Implantation of oversized closure device is easy to affect the atrioventricular conduction system, and bring about valve disorder causing III DHS atrioventricular block or tricuspid regurgitation congruent complications.

Conclusion: The objective of these reassessment studies was to investigate the influence of VSD and ASD closure directed by transeophageal echocadiography and resume the observation.

Through postoperative review and regular follow-up of 907 patients with successful closure operations, it is proved that VSD and ASD closure guided by esophageal echocardiography is safe, effective and feasible.

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Compliance with Ethical Standards

Conflict of interest The authors declare that they have no conflicts of interest with respect to this manuscript.

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