Original Article

Transthoracic minimally invasive closure for the treatment of ruptured sinus of Valsalva aneurysm: immediate and mid-term follow-up results

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Background: We aimed to evaluate the immediate and mid-term outcomes of transthoracic minimally invasive closure (TMIC) of ruptured sinus of Valsalva aneurysm (RSVA), which is a rare and mostly congenital heart disease.

Methods: From January 2014 to November 2020, 19 patients (16 males, 3 females) with RSVA were selected for TMIC and were followed up at our centre. Data were analysed from our prospectively collected database and clinical mid-term follow-up was obtained.

Results: Among these 19 cases, transthoracic echocardiography showed rupture of the right coronary sinus to the right atrium in 9 patients, non-coronary sinus rupture to the right atrium in 7 patients, and right coronary sinus rupture to the right ventricle in 3 patients. Most (13/19) cases were New York Heart Association (NYHA) functional class III or IV. The mean diameters of the defect from the aortic end and ruptured site were 8.8±3.0 and 6.4±2.6 mm, respectively. TMIC was attempted using ventricular septal defect (VSD)/patent ductus arteriosus (PDA) occluders 2–7 mm larger than the aortic ends of the defects. All patients were successfully treated by TMIC and achieved complete closure at discharge after a mean hospital stay length of 6.2±2.5 days. Seventeen patients were NYHA class I while 2 patients were NYHA class II. No cases of residual shunts, device embolization, infective endocarditis, or aortic regurgitation were observed during a median follow-up of 36 months (range, 16–84 months).

Conclusions: In appropriately selected cases with RSVA, TMIC is an attractive alternative to surgery, with a high technical success rate and encouraging short-term and mid-term outcomes. However, long-term follow-up is needed.

Keywords: Ruptured sinus of Valsalva aneurysm (RSVA); congenital heart disease; transesophageal echocardiography (TEE); minimally invasive; closure

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Introduction

Ruptured sinus of Valsalva aneurysm (RSVA) is a rare congenital heart disease caused by a congenital deficiency of muscular or elastic tissue in the aortic wall of the sinus of Valsalva. RSVA is more prevalent in Asia than in Western countries and usually occurs in adolescence or young adulthood (1). Unruptured sinus of Valsalva aneurysm (SVA) is usually asymptomatic. However, once

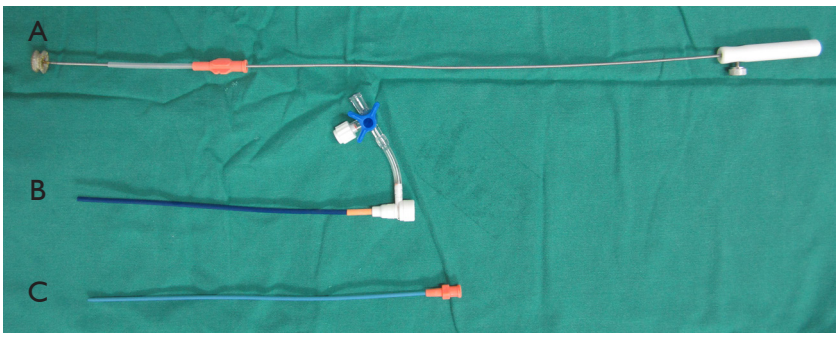

Figure 1 Delivery system. (A) Loading sheath with a muscular ventricular septal defect (mVSD) occluder. (B) Guide sheath. (C) Dilator and delivery sheath.

the aneurysm ruptures into one of the cardiac chambers, it can lead to a shunt from the aorta to the heart chamber, resulting in significant hemodynamic consequences and various symptoms such as chest pain, palpitation, dyspnoea, or even death (2). Aneurysm rupture may result in a high mortality rate if left untreated, but has a good prognosis after treatment. Therefore, once diagnosed, RSVA should be treated with surgical treatment under cardiopulmonary bypass (CPB) or percutaneous catheter closure (PCC) as early as possible (3). However, both treatment methods have advantages and disadvantages. Surgical treatment is more mature and has more indications, but it requires CPB and is associated with a high degree of trauma and the incision is not cosmetically appealing. As for PCC, although it has the advantages of minimal trauma and quick recovery, the outcomes are affected by a variety of factors, including a long delivery pathway, length of the catheterization route, and the use of radiation, which has resulted in its limited application.

Over the past decade, transthoracic minimally invasive closure (TMIC), a new approach involving surgical and transthoracic interventional treatment, has been developed which combines the advantages of both therapies. TMIC is not affected by the length of the catheterization pathway. Thus, this method expands the indications for an interventional approach. With the development of surgical occlusion technology and continuous updates to interventional facilities, an increasing number of doctors and patients are accepting this effective therapy, which offers minimal trauma and quick recovery. Since January 2014, TMIC has been performed at Lanzhou University Second Hospital to treat RSVA. The patients were followed up regularly in the outpatient clinic, and the procedure achieved satisfactory results. We present the following article in accordance with the STROBE reporting checklist (available at https://jtd.amegroups.com/article/view/10.21037/jtd-22-32/rc).

Methods

Patients and devices

From January 2014 to November 2020, a total of 27 patients with RSVA were admitted to our hospital. All patients underwent clinical examinations, electrocardiogram (ECG), chest radiography, and transthoracic echocardiography (TTE) with colour Doppler interrogation. The diameter of the ruptured of RSVA was measured at the aortic end as well as at the site of rupture under TTE or transesophageal echocardiography (TEE). Only those patients who did not have other related defects requiring surgical correction [e.g., ventricular septal defect (VSD) or significant aortic regurgitation (AR)] were selected. Additionally, patients with a huge RSVA (aortic origin >15 mm) and those with any suspicion or evidence of infective endocarditis (IE) were excluded. Eight patients were referred for surgical correction, including 3 with an associated VSD, 1 with moderate AR and aortic cusp prolapse, 1 with a large defect and multiple ruptured sites, 2 with IE, and 1 who refused surgery. Finally, 19 patients were treated by TMIC. Informed consent was obtained from all patients.

Three types of occlusion devices (Lifetech Scientific Co., Ltd., Shenzhen, China) were used in this study: (I) patent ductus arteriosus (PDA) occluder; (II) muscular VSD occluder; and (III) small-waist double disk VSD occluder (*Figure 1*).

All procedures performed in this study involving human participants were in accordance with the Declaration of Helsinki (as revised in 2013). The study was approved by

institutional ethics board of Lanzhou University Second Hospital (No. 2019A-172).

Procedure

TMIC was performed under general anesthesia and TEE guidance in the operating room. TEE was performed to reconfirm that RSVA occurred into the right ventricle (RV) or right atrium (RA) and to determine the shape, location, and diameter of the RSVA-RV/RA from both the aortic end and ruptured site. The aortic rim (the closest distance between the RSVA and the aortic annulus), aortic valve annulus, and coronary distance (the closest distance between the RSVA and the coronary ostium) were measured again before surgery, and then the appropriate surgical approach, proper device, and delivery system were selected. The size of the occluder selected was 2–7 mm larger than the narrowest diameter. The selected occluder, connected with the occluder cable, was screwed to the delivery cable and retracted into the loading sheath.

A 4.0-cm parasternal incision was made in the fourth right interspaces when RSVA occurred in the RA. Superficial tissues were dissected bluntly to enter the pleural space. Exposure was optimized with a mini-incision retractor. The pericardium was incised and cradled. Two purse-string sutures of 4-0 polypropylene (Ethicon, Somerville, NJ, USA) were placed on the RA after systemic anticoagulation with heparin (1.0 mg/kg). A right atrial puncture was performed within the purse-string sutures, and then the hollow probe was inserted immediately. First, the hollow probe-assisted delivery system was placed into the ascending aorta (AO) through the rupture opening. A flexible 0.035-inch guidewire was introduced into the AO through the hollow probe, and then the hollow probe was removed. Second, the delivery sheath was sent into the AO along the guidewire, and then the guidewire was pulled out. The occluder prepared in advance was implanted along the sheath. The first disc was opened in the AO and pulled back to the anchor at the rupture site, and another disc was opened next. When the shunt disappeared, the rest of the device was deployed immediately (*Figure 2*). Aortic valve regurgitation and the presence of a residual shunt were excluded before detaching the device. Device stability was ascertained by a push-pull maneuver and released when the assessment was satisfactory. The whole operation process was guided and monitored under TEE. After removing the device from the delivery cable, TEE was repeated to assess the position of the occluder, to identify any residual shunts, and to evaluate aortic valve function.

A 4.0-cm parasternal incision was made in the third left interspaces when RSVA protruded into the RV, and a pericardiotomy was performed. The free RV surface was exposed. In order to determine the puncture site, the RV free wall was gently palpated to locate the area of maximum tremor corresponding to the RSVA location. Two purse-string sutures were placed at this location. The other surgical steps were as described above.

Follow-up

All patients were monitored in the intensive care unit (ICU) until extubation. Patients were discharged 1–12 days after the procedure and received aspirin 100 mg once daily for 6 months. ECG, chest radiography, and TTE were performed before discharge. Out-patient follow-up examinations were performed at 1 month, 3 months, 6 months, 1 year, and annually thereafter and included clinical examination, ECG, chest radiography, and TTE. Surgery-related AR was defined as any grade of new AR or deterioration of existing AR beyond one grade.

Statistical analysis

Statistics All continuous variables are expressed as mean values and standard deviation or median with range as appropriate, and discrete variables are presented as percentages. The statistical analysis was performed using SPSS, version 22.0 (SPSS, Chicago, Illinois, USA).

Results

The detailed baseline characteristics of the 19 cases are summarized in *Table 1*. There were 16 males and 3 females aged 18–54 years (mean ± standard deviation 42.2±9.0 years). Most cases (10/19) were New York Heart Association (NYHA) class III, 6 were class II, and 3 were class IV (*Table 1*). A continuous systolic machinery-type murmur was detected at the left sternal border in all patients. One patient had a history of previous RSVA patch closure (9 years ago). The associated conditions included bicuspid aortic valve (BAV) (1/19), trivial AR (3/19), and mild AR (1/19). TTE revealed RSVA from the right coronary sinus (RCS) rupturing into the RV in 9 cases and into the RA in 3 cases, and also revealed RSVA from the non-coronary sinus (NCS) rupturing into the RA in 7 patients (*Table 1*). The mean diameters of the defect from the aortic end

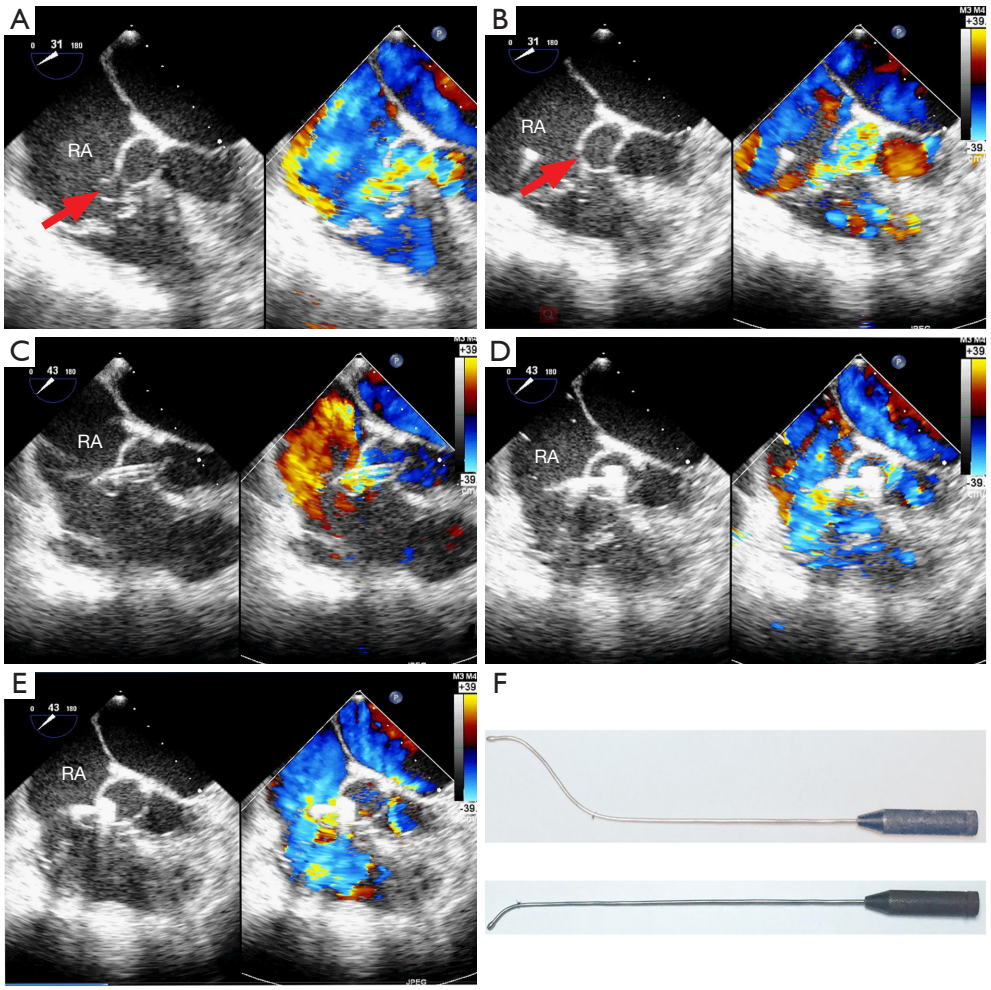

Figure 2 Sequential transesophageal echocardiography (TEE) and illustration images of transthoracic minimally invasive closure (TMIC) of the ruptured sinus of Valsalva aneurysm into the right atrium (RSVA-RA). (A) An echocardiographic view of "windsock"-like RSVA-RA. (B) The hollow probe-assisted delivery system guidewire was inserted into the RA, the hollow probe-assisted delivery system was placed into the ascending aorta (AO) through the rupture opening followed by a flexible 0.035-inch guidewire introduced into the AO through the hollow probe, and then the hollow probe was removed. (C) The delivery sheath was sent into the AO along the guidewire. (D) The device was advanced and opened with its left disc above the aortic valve. (E) The right disc was deployed across the RSVA-RA and the rest of the device was deployed as the shunt disappeared. (F) The hollow probe-assisted delivery system guidewire. Arrow indicates rupture. RA, right atrium.

and ruptured site were 8.8±3.0 mm (median 9.5 mm) and 6.4±2.6 mm (median 8 mm), respectively.

All of the 19 cases had successful occlusion of the RSVA, with PDA occluders used in 12 cases and a VSD occluder used in 7 cases. The chosen device was 2–8 mm (mean 4.3±1.7 mm) larger than the aortic end of the defect to better close the defect at the stouter aortic end. The mean procedure time was 40.8±9.0 min, the length of ICU stay was 20.8±5.7 h, and the length of postoperative hospital stay was 6.2±2.5 days. No procedure-related deaths, myocardial infarction, bleeding or hematoma, emboli, or other complications occurred during the operation. A trivial residual shunt was found in 1 case but disappeared the next day, which was confirmed by TTE (case 9). Two patients had trivial AR, and there was no increase during the follow-up period (cases 5 and 11). All patients achieved complete closure at discharge.

The median follow-up time of all cases was 36 months (range, 16–84 months). At the last follow-up, 17 cases were NYHA class I while 2 patients were class II. During

the follow-up period, there was no residual shunt, IE, progression of AR, or new AR.

Discussion

RSVA is a rare but well-recognized clinical entity that usually occurs between the third and fourth decade of life (4). There are obvious differences in ethnicity and sex among patients with RSVA (5). RSVA tends to occur more commonly in Asian countries, and the incidence has been reported to be 5 times higher among Asian populations than among Western populations (1). RSVA occurs mostly in men, and the ratio of males to females is [2–4]:1 (4,6,7). RSVA occurs mostly in the RCA, followed by the NCS, and rarely occurs in the left coronary sinus (LCS) (8). RSVA occurs most frequently in the RV, followed by the RA, and rarely ruptures in the left ventricle (9,10), and the results of our included population are similar to these reports. TTE plays a key first-line role in the diagnostic evaluation of suspected SVAs, as well as in serial follow-up of patients with nonruptured SVAs (11). With the increased availability of three-dimensional (3D) echocardiographic imaging, the addition of 3D imaging during both TTE and TEE will likely improve the assessment of SVAs. 3D echocardiographic imaging may enable better evaluation of the size and location of SVAs, as well as of the relationship with adjacent cardiac structures. Additionally, it is capable of rapidly and accurately detecting complications related to interventional and surgical repairs (12).

Patients with unruptured SVA usually do not have any symptoms, but nearly 80% of patients will have symptoms when the RSVA protrudes into one of the cardiac chambers (13,14). The most common symptoms are dyspnoea, orthopnea, palpitations, fatigability, palpitations, chest pain, and even sudden death (15). Death is usually due to acute heart failure (16). Adams *et al.* (17) documented that RSVAs require early surgical intervention since the mean survival period is 3.9 years if untreated. Therefore, early closure is recommended as soon as the diagnosis is confirmed. The conventional treatment approaches for RSVA mainly include surgical repair with patch closure under CPB and PCC with an occlude. There is still debate about which treatment is most appropriate for patients with RSVA (18).

Since 1956, surgical repair under CPB has become a mature approach for the treatment of RSVA, with a perioperative mortality rate between 1.9% and 3.9% (1,15,16), and the survival rate 10 years after surgery can reach up to 90% (8,9). However, surgical repair cannot prevent the need for sternotomy and CPB, with an average total length of hospital stay of 15 days and an average postoperative stay duration of 7 days (9,19). The average postoperative stay duration in our study was 5 days, and there was no need for CPB or any blood transfusion. Therefore, compared with surgical repair, the advantages of TMIC for RSVA include its minimally invasive nature and shortened length of hospital stay, and it eliminates the need for CPB and blood transfusion.

PCC of RSVA was first reported by Cullen *et al.* in 1994 and has recently been widely used in the treatment of RSVA (5,20-24). However, this technique requires a long delivery pathway and is performed under X-ray, which cannot accurately delineate the anatomical structure of tissues adjacent to the RSVA, and X-rays can be damaging to both patients and doctors. Moreover, PCC is difficult to convert to surgical repair when closure fails and cannot be performed for some patients with a prior history of allergies to contrast media. In contrast, transthoracic closure under TEE guidance can not only clearly define the anatomy of the RSVA and its adjacent structures, but can also shorten the delivery pathway and enable the occluder to be released easily in a more stable position, similar to findings reported by Liang *et al.* (25). In addition, the procedure can easily be converted to surgical repair if the closure fails.

Patients and device selection

RSVA is frequently associated with other cardiac conditions, such as VSD, AR, and tricuspid regurgitation (9,24,26). It is generally accepted that RSVA combined with VSD is a contraindication to PCC (27,28). Patients with an isolated RSVA and a maximum rupture diameter ≤16 mm were recommended to undergo the procedure in our study as the bigger device is worsening of pre-existing, development of new AR or coronary ostial pinching. Moreover, the distance between the ostium of the RCA and the ruptured site should be more than 5 mm, the distance between the aortic valve annulus and the ruptured site should also be more than 5 mm, and the distance from the aortic valve annulus to the aortic rim should be at least 1 mm.

Although we did not treat pregnant patients with aortic sinus aneurysm rupture, we believe that TMIC is a good alternative for patients with RSVA in earlier pregnancy according to the studies (28,29).

The selection of a suitable occluder is important for the efficacy of percutaneous closure of RSVA; however, no occluders have yet been specially designed for this rare anomaly. At present, VSD occluders and PDA occluders are

Table 1 The baseline characteristics and clinical results of the 19 patients

Case No.	Age/ gender	NYHA class	Previous surgeries	Associated lesions	Rupture location	Rupture size (aortic origin/ rupture site) (mm)	Occluder size (mm)	Residual shunt/ procedure-related AR at discharge	Residual shunt/ procedure-related AR at follow-up	Follow-up (months)	NYHA class during follow-up
1	54/M	III	No	No	NCS into RA	6/4	12/10 PDA	No/no	No/no	84	I
2	43/F	III	No	No	NCS into RA	10/9	14/12 PDA	No/no	No/no	78	I
3	45/M	III	No	No	RCS into RA	6/4	10/8 PDA	No/no	No/no	69	I
4	45/M	II	No	Trivial AR	RCS into RV	10/8	14/12 PDA	No/no	No/no	62	I
5	45/M	IV	No	Trivial AR	RCS into RA	9/10	14 mVSD	No/trivial	No/trivial	56	II
6	48/F	IV	No	No	RCS into RA	9/5	10/8 PDA	No/no	No/no	48	I
7	53/M	III	No	No	NCS into RA	5/4	12/10 PDA	No/no	No/no	46	I
8	48/M	III	No	No	RCS into RA	11/8	16/14 PDA	No/no	No/no	38	I
9	48/M	III	No	BAV	RCS into RA	4/4	6/4 PDA	Small*/no	No/No	37	I
10	35/M	II	No	No	NCS into RA	5/3	6 mVSD	No/no	No/no	36	I
11	33/M	IV	No	Mild AR	RCS into RV	15/13	20/18 PDA	No/trivial	No/trivial	36	II
12	44/M	III	No	Trivial AR	NCS into RA	10/8	12/10 PDA	No/no	No/no	33	I
13	48/M	III	Post-RSVA patch closure	No	RCS into RV	6/5	8 mVSD	No/no	No/no	31	I
14	36/M	II	No	No	RCS into RA	10/4	12 mVSD	No/no	No/no	31	I
15	34/M	II	No	No	RCS into RA	12/7	18/16 PDA	No/no	No/no	24	I
16	18/M	II	No	No	RCS into RA	9/6	10 mVSD	No/no	No/no	24	I
17	42/M	III	No	No	RCS into RA	12/6	14/12 PDA	No/no	No/no	23	I
18	51/M	III	No	No	NCS into RA	12/8	14 mVSD	No/no	No/no	16	I
19	31/F	II	No	No	NCS into RA	7/5	8 mVSD	No/no	No/no	16	I

*, trivial residual shunt disappeared the next day. NYHA, New York Heart Association; AR, aortic regurgitation; M, male; F, female; NCS, non-coronary sinus; RA, right atrium; PDA, patent ductus arteriosus; RCS, right coronary sinus; RV, right ventricle; mVSD, muscular ventricular septal defect; RSVA, ruptured sinus of Valsalva aneurysm.

the most frequently used for the closure of RSVA in most reports (15,22,25). The effectiveness of the closure is not only dependent on aneurysm size but also on the relationship of the aneurysm with the adjacent structures and the shape of the RSVA. Since the shape of the RSVA under TEE was either a "windsock" or funnel-shaped deformity, the PDA occluder or muscular VSD occluder was considered to be best suited for this defect (25). A ductal occluder or a muscular VSD occluder should be chosen for a windsock RSVA, while a small-waist double disk or muscular VSD occluder might be chosen for a funnel-shaped RSVA with a long or short aortic rim. To avoid injuring the aortic valve, the left disc should be opened above the aortic valve, the device should be firmly attached to the rupture site, and there should be no interference with the adjacent structures, such as the aortic valve and the opening of the coronary artery.

Limitations

This study demonstrates that TMIC for RSVA achieved good results; however, this study also has some limitations. First, this is a single-center, retrospective study and some patients did not adhere to the strict follow-up schedule after the operation. Second, this study includes a relatively large series of patients who underwent TMIC of RSVA, with a mean follow-up of approximately 30 months. The short-term and mid-term clinical outcomes are encouraging, but the long-term outcomes are still unclear. Therefore, the multi-center clinical trials and a larger sample size and long-term follow-up are needed to confirm the results.

Conclusions

The preliminary results of TMIC of RSVA indicate that, in appropriately selected patients with RSVA, especially those with an isolated RSVA, a single rupture, a rupture size no more than 15 mm, and a prior history of allergic reaction to contrast media, TMIC is a safe and effective alternative treatment with a high technical success rate and encouraging immediate and mid-term outcomes. However, long-term follow-up evaluations are still necessary, and this approach should be directly compared with surgery and PCC in terms of safety and efficacy.

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Footnote

Reporting Checklist: The authors have completed the STROBE reporting checklist. Available at https://jtd.amegroups.com/article/view/10.21037/jtd-22-32/rc

Data Sharing Statement: Available at https://jtd.amegroups.com/article/view/10.21037/jtd-22-32/dss

Conflicts of Interest: All authors have completed the ICMJE uniform disclosure form (available at https://jtd.amegroups.com/article/view/10.21037/jtd-22-32/coif). The authors have no conflicts of interest to declare.

Ethical Statement: The authors are accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved. All procedures performed in this study involving human participants were in accordance with the Declaration of Helsinki (as revised in 2013). The study was approved by institutional ethics board of Lanzhou University Second Hospital (No. 2019A-172). Informed consent was obtained from all patients.

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