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ORIGINAL ARTICLE

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Clinical outcomes of percutaneous or surgical closure of ruptured sinus of Valsalva aneurysm

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Abstract

Objective: To evaluate the clinical efficacy, safety, and long-term outcomes of percutaneous closure (PC) and surgical repair of ruptured sinus of Valsalva aneurysm (RSVA).

Methods: Eighty-five consecutive patients with RSVA were included in this study. Patients were considered candidates for PC if they met the criterion, surgical repair was performed on patients who were unsuitable or failed PC. Of them, 30 patients underwent PC, while the other 55 patients had surgical repair.

Results: RSVA was successfully occluded in 29 of 30 patients who were treated by PC. The mean narrowest diameter at the ruptured site was 6.45 ± 1.60 mm measured by aortography. One patient developed serious occluder-related aortic regurgitation and underwent surgery. The success rate of the interventional approach was 96.7%. In the surgical group, 23 patients underwent repair of combined RSVA and ventricular septal defect. The hospital mortality rate of the surgical approach was 3.57%. During a median follow-up of 83 months (8–152 months), the improvement in NYHA functional class in the PC group was significantly greater than those in the surgical group ($P < .01$). One patient died of infective endocarditis in the surgical group. There were no further serious complications.

Conclusions: PC is a safe alternative to surgical repair for patients with isolated RSVA. Surgical repair is more suitable for those who have multiple cardiac lesions requiring surgical treatment or failed PC.

KEYWORDS
aneurysm, outcome, percutaneous, surgery, Valsalva

1 | INTRODUCTION

Rupture of sinus Valsalva aneurysm (RSVA) is a rare congenital cardiovascular malformation. Sinus Valsalva aneurysm (SVA) is usually caused by a congenital deficiency of muscular and elastic fiber tissue in the aortic wall leading causing aneurysmal formation. The unruptured SVA is usually asymptomatic. However, when it ruptures into one of the cardiac chambers, it causes a large left-to-right shunt and severe congestive heart failure.[1] Therefore, once diagnosed, SVA should be treated by percutaneous closure (PC) or surgical repair as early as possible.[2]

Since the first successful surgical repair was reported by McGoon in 1956, it has been the conventional treatment for RSVA. However, potential morbidity from cardiopulmonary bypass and sternotomy, the risk of general anesthesia and patch leak may occur requiring a second operation.[3,4] PC of RSVA was first attempted by Cullen et al.[5] in 1994 using a Rashkind umbrella. Thereafter, many models of occluders have been developed for PC of RSVA. In recent years, some studies have shown that PC of RSVA has a good prognosis from immediate and short-term follow-up results. However, there is inadequate literature

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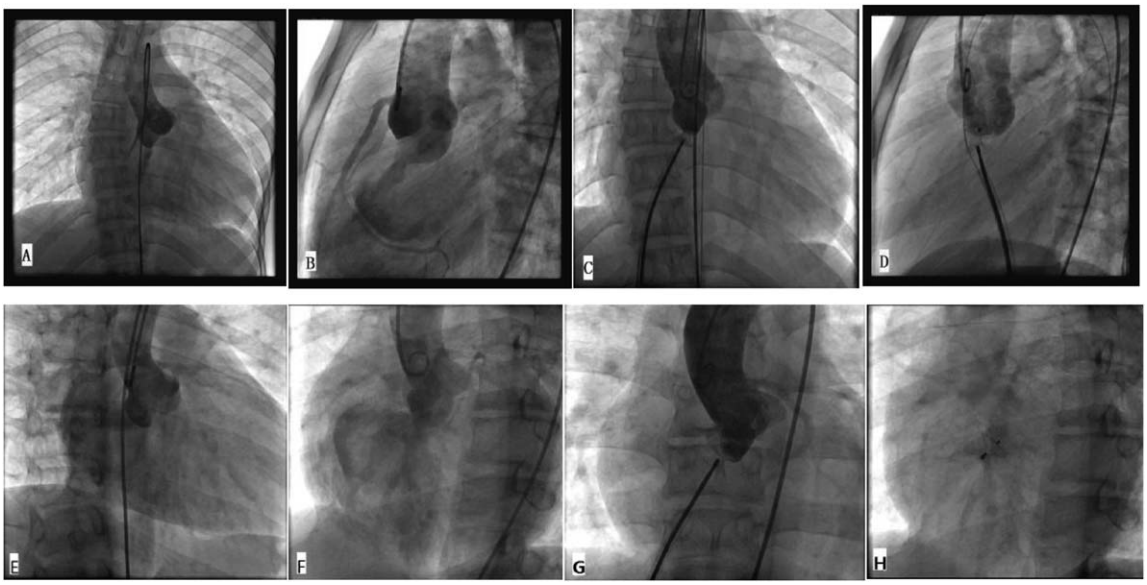

FIGURE 1 The aneurysm of noncoronary sinus ruptured into right atrium (Patient 1: A,B,C,D; Patient 2: E,F,G,H), which was shown by an aortagram in the right anterior oblique (A,E) and lateral view (B,F); Repeated aortagrams showed complete occlusion of RSVA with PDA occluder (C,D) and small waist double disk VSD occluder (G) in the right anterior oblique and lateral view. Image (H) shows the VSD occluder after the release

about the long-term follow-up results for this technique. Thus, the objective of this study is to evaluate the comparative clinical efficacy and long-term outcomes by using PC or surgical repair of RSVA.

2 | METHODS

2.1 | Patients

From October 2003 to January 2016, a total of 85 patients who were diagnosed with RSVA in our single center were consecutively enrolled in the study. Patients were considered candidates for PC if they met the criterion, including (a) body weight >10 kg; (b) drainage sites in the right coronary sinus (RCS) or noncoronary sinus (NCS), ruptured into right atrium or right ventricle, and maximum diameter of the defect by angiography cannot exceeds 10 mm; (c) SVA without involving aortic valve or annulus, distance from aortic valve annulus to the ruptured site ≥ 7 mm; (d) distance from the ostium of the right coronary artery to the ruptured site ≥ 5 mm; (e) without other cardiovascular diseases requiring surgical treatment. Surgical repair was performed on patients who were unsuitable or failed PC. The Ethics Committee of our hospital approved the study and the choice of closure was discussed with the patients and consents were obtained.

Medical records, including medical history, physical examination, chest x-ray, echocardiography, electrocardiogram, cardiac catheterization, angiography, and procedure operating notes were collected.

2.2 | Device

Two types of occluder were used for PC in the study. One was a domestic modified small waist double-disk ventricular septal defect occluder (VSD; Shanghai Shape Memory Alloy Ltd, Shanghai, China), which was designed based on the Amplatzer VSD occluder and filled with five layers of polyester film in the nickel titanium alloy stent. The left and right ventricular disks were asymmetric, the diameter of left ventricular disk is 8 mm larger than the waist; the diameter of right ventricular disk is 4 mm larger than the waist, the height of the waist is 4.5 mm. The occluder has been approved by China Food Drug Administration in 2003 and has been widely used for VSD in China. The other type is the domestic mushroom type patent ductus arteriosus (PDA) occluder (Shape Memory Alloy Materials Co., Ltd., Shanghai, China). It is also made of Nickel titanium alloy wire and is self-expandable. Like a mushroom single umbrella, the diameter of aortic end is 2–3 mm larger than the height of waist. The waist of occluder expands like a cylinder with a length of 7–8 mm.

2.3 | Procedure

All patients underwent attempted PC or surgical repair of RSVA after obtaining informed consents. The procedure of PC was carried out under local anesthesia by using both fluoroscopy and transthoracic Echocardiography (TTE) Guidance. Intravenous heparin (100 IU/kg) was given routinely. In addition to the patients who had aortic valve disease and right ventricular outlet obstruction, right and left heart catheterization were routinely performed to obtain the hemodynamic parameters including right and left heart pressure and oxygen saturation, and calculate the pulmonary-to-systemic flow ratio (Qp/Qs). Then aortic root angiography was performed using a 6F pigtail catheter (Figure 1A,B,E,F) to further clarify the structure of RSVA and aortic valve. According to the measurement of the aortic angiography and TTE, an appropriately sized occluder with delivery cable was advanced via the delivery sheath from the venous route, and was deployed in the opening of the RSVA. The size of the occluder selected was 2–7 mm larger than the narrowest diameter. The aortic root angiography (Figure 1C,D,G,H)

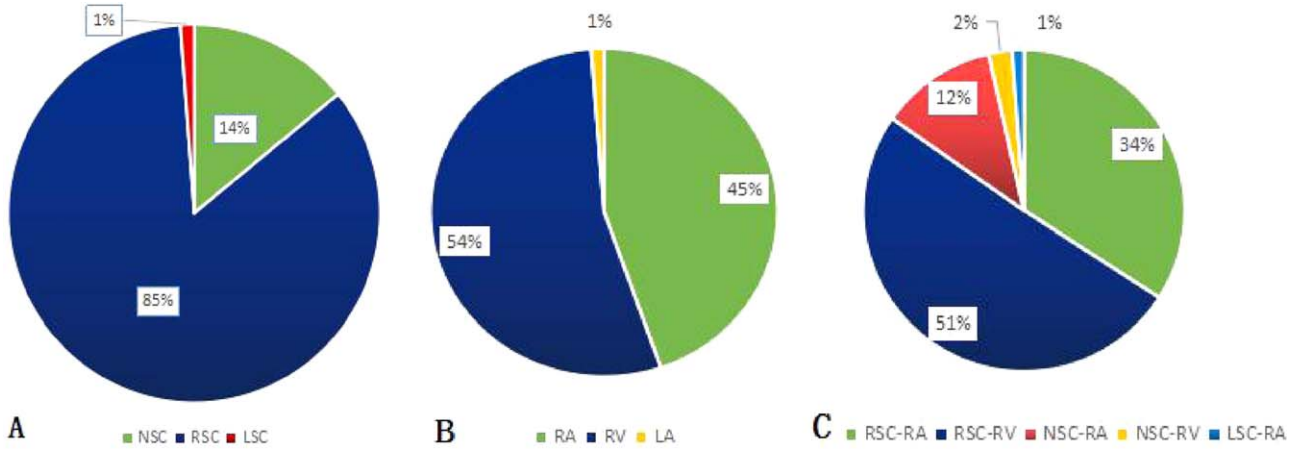

FIGURE 2 The characteristics of the ruptured and drainage sites for RSVA. (A) Ruptured Sinus origins; (B) Drainage sites; (C) The incidence of each type. Abbreviations: NSC, noncoronary sinus; RSC, right coronary sinus; LSC, left coronary sinus; RA, right atrium; RV, right ventricle; LA, left atrium

was repeated to confirm a complete occlusion of the RSVA without aortic valve regurgitation. The occluder was then released from the cable after confirming that there was no significant AR, tricuspid regurgitation (TR), or any encroachment on right coronary arteries as seen on the TTE or the control angiography. When the occluder does not match the size or the type of RSVA, we retrieve the occluder through the delivery sheath and replace it with another appropriate occluder. Prophylactic antibiotics were routinely administrated after the procedure for 2 days. Oral administration of aspirin (3–5 mg/kg) was given for 6 months.

The procedure of surgical repair was performed under general anesthesia using patch repair of the ruptured Vasalva aneurysm using extracorporeal circulation. VSD or PDA repair may be performed along with RSVA repair. Aortic valvuloplasty, or replacement or tricuspid valve repair were peformed for those who had combined aortic valve disease or tricuspid insufficiency. Deoppilation with right ventricular outflow was carried out for those who had right ventricular outflow tract obstruction.

All patients had repeat TTE at discharge, 1-, 3-, 6- months, and annually thereafter. Device related complications were carefully recorded.

2.4 | Statistical analysis

The data were analyzed with statistic software SPSS 19.0 (Chicago, Illinois). All continuous variables are expressed as mean values and standard deviation, which was performed by independent sample student *t*-test. Discrete variables are presented as percentages, which was performed by chi-square test or Fisher's exact test. A P value $< .05$ was considered statistically significant. A P value $< .01$ was considered statistically more significant.

3 | RESULTS

3.1 | Baseline clinical characteristics

Eighty-five patients (59 male and 26 female) with RSVA (37.65 ± 11.96 years old) were selected for inclusion in the study. Twenty-nine patients underwent PC for RSVA successfully, the remaining 56 patients had surgical repair. There were no significant differences in age and gender between the two groups. The characteristics of RSVA are shown in Figure 2. RSVA from RCS was found in 72 patients (85%), from NCS in 12 (14%), and from the left coronary sinus (LCS) in 1 (1%). The draining chamber was right ventricle in 46 (54%), right atrium in 38 (45%), and left atrium in 1 (1%) of patients. The RSVA from RCS ruptured into right ventricle was the most common type, accounting for about 51%, and RCS ruptured into right atrium in 29 (34%); NCS ruptured into right atrium in 10 (12%), and right ventricle in 2 (2%). Only one patient (1%) had LCS ruptured into left atrium.

3.2 | Clinical characteristics in PC group

The detailed clinical characteristics of patients in the PC group are shown in Table 1. 30 patients were treated with PC. A continuous machinery-type murmur was heard at the left sternal border in all patients. Symptoms were chest pain in 3, palpitation in 10, fatigue in 13, and dyspnea in 15 patients. Thirteen patients were asymptomatic. RSVA from RCS into right ventricle in 15 and right atrium in 7; NCS ruptured into the right atrium in 7. One patient underwent PC for RSVA and PDA concomitantly. As is shown in Table 2, one patient developed severe aortic insufficiency after PC and ultimately underwent surgical repair and aortic valve replacement. Therefore, the success rate of PC was 96.7%. In the PC group, the diameter at the ruptured site varied from 4 to 10 mm (6.45 ± 1.6 mm) and the operation time was (60.34 ± 12.10) min. The Qp/Qs was 2.23 ± 0.60 (range, 1.28–2.78) and the pulmonary artery pressure was 27.56 ± 9.20 mm Hg. Two types of device were used in the study: small-waist double-disk VSD occluders in 18 cases (the size of the occluders was 9.5 ± 2.2 mm) and PDA occluders in 11 cases (the aortic end diameter of the occluders was 14.38 ± 2.16 mm). There was only one patient with mild residual shunt in 29 patients with PC.

3.3 | Clinical characteristics in surgical group

A total of 56 cases received surgical treatment. The diameter of RSVA varied from 5 to 20 mm and mean (9.18 ± 3.12) mm. RSVA originated from RCS in 50 patients, which ruptured into right ventricle in 28 and

TABLE 1 Comparison of baseline between surgical group and PC group

Data	Surgical group	PC group	*P* value
Patients (*n*)	56	29	
Sex (F/M)	19/37	8/21	.55
Age (years)	37.8 ± 11.9	36.7 ± 11.1	.44
Defect-location [*n* (%)]			.09
RCS-RA	22 (39.2)	7 (24.1)	
RCS-RV	28 (50)	15 (51.8)	
NCS-RA	3 (5.4)	7 (24.1)	
NCS-RV	2 (3.6)	0 (0)	
LCS-LA	1 (1.8)	0 (0)	
NHYA functional class	2.73 ± 0.77	2.59 ± 0.63	0.16
I [*n* (%)]	0(0)	0(0)	
II [*n* (%)]	19 (33.9)	13 (44.8)	
III [*n* (%)]	26 (46.4)	14 (48.3)	
IV [*n* (%)]	11 (19.6)	2 (6.9)	
Combined with VSD [*n* (%)]	13 (23.2)	2 (6.9)	0.06
Diameter of the ruptured site (mm)	9.18 ± 3.12	6.45 ± 1.6	<0.01
Qp/Qs ratio	2.58 ± 0.54	2.23 ± 0.60	<0.01
Follow Up time (months)	75.5 ± 38.3	89.4 ± 34.9	0.10

Abbreviations: F, female; M, male; RCS, right coronary sinus; NCS, non-coronary sinus; LCS, left coronary sinus; VSD, ventricular septal defect; RA, right atrium; RV, right ventricle.

right atrium in 22; and from the NCS in 5, which ruptured into right atrium in 3 and right ventricle in 2. Only one patient had LCS rupture into left atrium. As is shown in Table 2, 43 patients (76.79%) had other heart diseases. They all underwent the appropriate surgical treatments. The incidence of serious complications and mortality were 7.14%, including two deaths (one died of low cardiac output syndrome, the other died of respiratory failure) and two cases with pericardial tamponade needing pericardiocentisis.

3.4 | Follow-up outcomes

The baseline of NYHA functional class were (2.59 ± 0.63) and (2.73 ± 0.77) between the PC group and the surgical group, ($P = .16$). The patients in the two groups were followed up for (75.5 ± 38.3) months and (89.4 ± 34.9) months, respectively. On a median follow-up of 83 months (8–152 months), the NYHA functional class in each group both significantly improved at last follow-up [(2.59 ± 0.63) vs (1.34 ± 0.48); (2.73 ± 0.77) vs (1.91 ± 0.60), respectively, both $P < .01$]. With the exception of one death from infective endocarditis in the surgical group at follow-up, there were no residual shunts, device embolization, occluder displacement, aortic insufficiency, arrhythmia, death, or other serious complications.

4 | DISCUSSION

RSVA is a rare but well-recognized clinical entity, which usually occurs in adolescence or early adulthood. Most frequently, it is congenital in origin due to either a congenital absence of continuity between the aortic media and the annulus fibrosis, or a developmental structural defect in the aortic annulus itself, which can gradually give way to form an aneurysm. Patients with unruptured SVA are usually asymptomatic. However, RSVA ruptures into one cardiac chamber will cause profound hemodynamic change and worsening of symptoms. There are obvious differences for patients with RSVA in race and gender. RSVA occurs mostly in men, the ratio between male with female is 3:1.[6] The incidence of RSVA in Asian population is 5 times higher than that in western populations. It is reported that the average age of onset was 32 years of age in Chinese, 27 years of age in Japanese,[7] and 42 years of age in Americans.[8] Young men in Asian are at high risk of RAVA. In the present study, the mean age of onset for the 85 patients was 37 years of age and 69% were male This result is similar to that reported in the literature.

SVA is found most often in RCS (65%–85%), less often in NCS (10%-30%), and least often in LCS (only 1%–5%).[9,10] For Drainage sites, SVA largely ruptured into right ventricle (63%). Most common is RCS rupture into the right ventricular outflow tract, followed by the right atrium (32%),[11,12] and rarely rupture into left ventricular, VSD, pericardial cavity, or pulmonary artery.[13] In addition, RSVA often coexists with other congenital heart malformations, such as VSD (30%–60%), bicuspid aortic valve (10%), aortic valve regurgitation, pulmonary stenosis, coarctation of the aorta, and atrial septal defect. In our study, 85% patients with RSVA were found in RCS. Subarterial type VSD (18 cases)

TABLE 2 Coexisting disease and surgeries performed in surgical group

Coexistent lesions	Procedures	No. of patients (*n*)
Surgical group (*n*=56)		
Ventricular septal defect (*n*=23)	Suture repair	6
	Patch repair	17
Aortic valve disease (*n*=13)	Aortic valve replacement	10 (one PC failure)
	Aortic valvuloplasty	2
	Bentall	1
Tricuspid insufficiency	Repair	5
Mild tricuspid insufficiency	No treatment	4
Right ventricular outlet obstruction	Enlarge with patch	1
Patent ductus arteriosus	Ligation	1
Infective endocarditis	Antibiotic	3
Percutaneous closure group (*n*=30)		
Ventricular septal defect	No treatment	2
Aortic regurgitation	No treatment	2
	Aortic valve replacement	1
Patent ductus arteriosus	Occlusion	1

was found more frequently than the other type. The perimembrane type in 4 and the supracristal type in 3. As is reported in the literature, in Chinese and Indian patients with RSVA, VSD was almost always subarterial whereas perimembranous was more common in western patients.[14] In addition, 15 patients with aortic valve disease were found nine patients with tricuspid insufficiency and two patients with PDA.

RSVA occurs frequently with other cardiac lesions requiring surgical approach, if sufficient medical treatment is given, it is still unable to improve heart function, surgical treatment should be performed after positive preoperotive preparation as soon as possible. Therefore, surgical repair under cardiopulmonary bypass is still one of the mature approaches in the treatment of RVSA and has a fine long-term outcome after surgery, regardless of the onset status or association with other cardiac lesions. The mortality in RSVA patients undergoing open heart surgery is approximately 3%. The survival rate of 10 years after surgery could reach up to 90%.[15,16] Our study suggests conventional surgical repair offers excellent results for closure of ruptured SVA with low operative mortality and morbidity.

Although there is no special occluders and commonly recognized standards for selecting the type and size of occluders for PC of RVSA, percutaneous approaches have achieved good results have increasingly been reported in several heart centers. Currently, VSD occluders and PDA occluders were widely used for PC of RSVA in most reports. The effectiveness of PC is not only entirely dependent on the size but also related to the adjacent tissue. The standard of the success is to close the crevasse completely, without affecting the surrounding tissue. Hence, the size and type of the occluders should be individually selected based on individual patient requirements so as to increase the success rate and reduce the complications. An appropriate occluder should be chosen at least 2 mm larger than the entrance diameter of RSVA according to the angiographic features. Selected VSD and PDA occluders were 2–5 mm and 2–7 mm larger than the rupture opening of aneurysm respectively in the present study.

Patients in window-like or aneurysmal type with surrounding soft tissue were preferably treated with small-waist double disk VSD occluders. The small-waist matches the entrance diameter of window-like and aneurysmal RSVA. Its shape recovers well after release and does not obstruct enough to affect aortic valve function and its left side can cover all the left inlets completely with little interference on aortic valve morphology and function.[17] PDA occluders with a long connecting waist should be preferred in patients with tubular shape, long bag, or close to tricuspid valve, which could not affect tricuspid valve function and avoid the situation that its aortic end is pulled into the side of aneurysm resulting in the formation of residual shunt or the occluder abscission. Therefore, on the basis of the anatomy of ruptured SVA, different types of occluder selection will achieve a better sealing effect. In our study, both small waist VSD occluders and PDA occluders had a high success rate of 96%. The NYHA functional class of the PC group was improved in Classes I–II at last follow-up. There was no infection endocarditis, residual shunt, thrombosis, occluder abscission, and device related aortic valve and other serious complications found, showing good long-term outcome and lower complication rate compared to the surgical group.

As we known, the advantages of percutaneous closure of RSVA lie in minimal invasiveness, a shorter time of hospital stay, an avoidance of extracorporeal circulation, and blood transfusion, and better economic benefits compared with surgical repair.[18] However, occluder implantation may have a certain impact on the surrounding anatomy. Zhang et al.[19] described a failed case with a 14 mm diameter defect in which an 18–20 mm PDA occluder was used in PC. After the procedure, severe AR developed requiring aortic valve replacement. The main reasons for interventional treatment failure in our cases were the large size of the defect and the use of a relatively large occluder causing traction on the aortic annulus, resulting in increased aortic regurgitation and enlargement of the left ventricle. Therefore, if the diameter of the RSVA defect exceeds 10 mm and the surrounding anatomy of SVA is complex, we recommend surgical treatment rather than percutaneous closure.

In our study, we compared the long-term follow-up of traditional surgery and PC of RSVA using modified double-disk VSD occluders and PDA occluders. As we know, the present study is a relatively large study of patients undergoing PC and surgical repair of RSVA. This study showed PC or surgical repair of RSVA are both feasible and safe with satisfactory long term follow-up results. PC is a safe and effective alternative to surgical repair for isolated RSVA. Our study demonstrated significant benefits of PC of RSVA, however, Our study also had some limitations. First, it was not a randomized controlled study. The patients were not randomly assigned to the PC group or the surgical group in the present study, Surgical repair was performed on the patients who were unsuitable or failed PC, which might cause a large sample error in comparison between the two groups. Second, the patients were included from a single center, which may not be universally representative. Therefore, more randomized, multicenter, controlled clinical trials are needed to compare the advantages and disadvantages of the two kinds of procedures.

5 | CONCLUSIONS

This study showed PC or surgical repair of RSVA are both feasible and safe with satisfactory long term follow-up results. PC is a promising alternative to surgical repair in appropriately selected patients. This has the advantages of minimal invasiveness, less serious complication, an avoidance of extracorporeal circulation and better economic benefits compared with surgical repair. However, patients with the diameter of rupture opening exceeding 10 mm, combined with other cardiac lesions, or with complex anatomy should undergo surgical repair.

CONFLICT OF INTERESTS

The authors declared that they have no conflicts of interest to this work. We declare that we do not have any commercial or associative interest that represents a conflict of interest in connection with the work submitted.

AUTHOR CONTRIBUTIONS

Drafted the article: Xiao

Acquired data: Xiao, Wang, Zhang, Han, Cui, Zhang, Hou

Analyzed and interpreted data: Xiao, Zhu

Approved the submitted manuscript: Xiao, Zhu, Wang, Zhang, Han, Cui, Zhang, Hou

Conceived the project and design: Zhu

Critically revised the manuscript for important intellectual content: Zhu, Wang, Zhang, Han, Cui, Zhang, Hou

Contributed to the design: Wang, Zhang, Han, Cui, Zhang, Hou

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