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RESEARCH

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Coronary protective effect of the J-Valve during transcatheter aortic valve implantation for patients with aortic stenosis and low coronary artery openings

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Abstract

Background In recent years, transcatheter aortic valve implantation (TAVI) has become a widely used treatment for low-risk elderly patients. As an alternative to TAVI via the femoral artery, transapical TAVI (TA-TAVI) is a better surgical choice for patients with severe vascular diseases. The J-Valve assists doctors in completing valve implantation easily using its positioning locator device, which prevents the self-leaflet from approaching the sinus wall. This function acts as coronary artery protection to avoid coronary occlusion. However, the clinical prognosis of J-Valve implantation for patients with aortic valve stenosis and low coronary openings is unclear.

Methods A retrospective analysis was performed on 30 patients with aortic stenosis (AS) and coronary openings measuring ≤ 10 mm in height. All patients underwent TA-TAVI with J-Valve implantation. Patients were screened using preoperative computed tomography three-dimensional imaging of the aortic root, and the safety and efficacy of the procedure were evaluated. The collected indexes included patients' general data, cardiac function, preoperative imaging parameters, intraoperative data and postoperative short-term prognosis.

Results Of the 30 patients in the study successfully underwent TA-TAVI and J-Valve implantation. Two patients required temporary cardiopulmonary bypass assistance during the operation due to heart failure. The implant success rate was 100%, and there were no deaths within 30 days postoperatively. No patients experienced intraoperative or postoperative coronary artery occlusion. Postoperative echocardiography, physiological state and laboratory test results indicated that all patients recovered well. The electrocardiograms remained normal after TA-TAVI, and heart function improved within 30 days.

Conclusion Transapical TAVI with J-Valve implantation is a safe and effective treatment option for patients with AS and a low coronary artery opening. Preoperative coronary artery evaluation and the locators of the J-Valve are crucial in preventing coronary artery occlusion. This treatment regimen provides beneficial outcomes and warrants further multi-centre clinical research in the future.

Keywords Transcatheter aortic valve implantation, Aortic stenosis, Transapical, Low coronary artery opening, J-Valve

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Introduction

Aortic valve disease pathologies are principally divided into aortic stenosis (AS) and aortic regurgitation (AR), with AS accounting for the vast majority of cases [1, 2]. For a long time, surgical aortic valve replacement has been regarded as the preferred treatment for AS, improving patients' quality of life and overall survival [3]. However, more than 30% of patients with severe AS symptoms are unable to undergo this procedure due to advanced age, left ventricular dysfunction and other organ dysfunctions [4]. In recent years, transcatheter aortic valve implantation/replacement (TAVI/R) has become the first choice for patients at high risk for open heart surgery [5]. Currently, the common approaches of TAVI are divided into antegrade via a vein, retrograde via an artery and the apical approach. The axillary and jugular approaches carry a high risk of bleeding, and the axillary approach also increases the risk of stroke [6, 7]. The carotid approach is associated with high 30-day mortality and neurovascular complications. For cases of simple AR, low coronary artery openings and small peripheral blood vessels, the femoral artery approach for TAVI is not suitable. Transapical TAVI (TA-TAVI) offers distinct advantages, including a reduced risk of coronary artery occlusion [4]. Although it requires a mini-incision, numerous studies have demonstrated that it is effective and safe for patients with AS/AR who are typically not suitable for traditional surgery [8–11]. Coronary artery occlusion, a severe complication of TAVI, significantly increases mortality, especially in patients with low coronary artery openings (≤10 mm) [12]. Preoperative evaluation and intraoperative coronary artery protection are particularly critical to avoid this complication [13].

A series of second-generation TAVI devices have been gradually developed, including Acura, Allegro, the Yena Valve and the J-Valve [14]. The J-Valve is equipped with three unique positioning parts that facilitate easy placement into the sinus [15]. These components, known as locators or grippers, include upper grippers that provide an innovative guiding system and a unique anchoring mechanism. The self-expanding Nitinol bracket ensures a close fit, and the lower sealing ring prevents blood leakage. The J-Valve offers significant advantages for TA-TAVI surgery through its unique design, enhancing implantation accuracy. These characteristics make the J-Valve a valuable option for complex cases requiring TAVI via the apical approach. With this special design, the J-Valve is suitable for patients with AS or AR and normal coronary openings, overcoming the limitations of TAVI in this patient population. Implantation of the J-Valve provides definitive coronary protection and may be a new choice for high-risk patients prone to coronary artery occlusion [16, 17]. Early results using the J-Valve have been validated by some hospitals, but studies on its efficacy in patients with AS and low coronary openings are still rare [18].

In our study, a retrospective analysis was conducted on the clinical outcomes of patients with low coronary artery openings (≤10 mm) screened through preoperative three-dimensional computed tomography (CT).

Materials and methods

Study participants

The clinical information of 30 patients with AS who underwent TA-TAVI using the J-Valve (JC Medical, suzhou, China) between January 2020 and April 2022 was retrospectively collected. The inclusion criteria were as follows: (1) symptomatic patients with severe AS requiring intervention according to ESC/EACTS guidelines [19], and (2) those with difficulties in femoral or other approaches. The exclusion criteria were as follows: (1) patients with acute myocardial infarction within 1 month postoperatively, (2) those with a recent history of stroke or transient ischemic attack (less than 3 months after surgery) and (3) those with contraindications to anticoagulation and antithrombotic therapy. After preoperative imaging screening, 30 patients with coronary artery openings (height ≤ 10 mm) who were treated with TA-TAVI using the J-Valve were included. This retrospective study was reviewed and approved by the Ethics Committee of Mudanjiang Cardiovascular Disease Hospital.

Operative methods

All patients were intubated under general anaesthesia in a hybrid operating room. A small left anterolateral chest intercostal incision was made at the corresponding position of the left apex, and the pericardium was opened and suspended using sutures. A purse-string suture was placed at the apex of the left ventricle, and a guide wire was inserted in the centre, which was confirmed as crossing the aortic valve using echocardiography. The guide wire was advanced to the descending aorta using a 6 F Amplatz-JR4 catheter, and a super-stiff wire was exchanged. Aortic valve pre-dilatation was performed in all patients with AS. The appropriate J-Valve size was selected based on the perimeter of the aortic annulus measured through CT angiography by injecting contrast agent into elbow vein. The valve locators were loaded into the three sinuses, and the valve was then released. Angiography was performed, and the flow rate and perivalvular leakage were assessed using ultrasound. Successful implantation was defined as the placement of a single J-Valve in an appropriate position without obvious hemodynamic abnormalities, coronary artery obstruction or acute myocardial infarction. There were no deaths, reinterventions, surgical treatments or severe cardiovascular and cerebrovascular complications within 30 days postoperatively.

Table 1 General clinical data and medical history of patients

Project		*N*=30
Demographics	Age (years)	72.00 ± 3.20
	Male	8(26.7%)
	Female	22(73.3%)
	BMI	24.5 ± 4.05
	Height (cm)	155.23 ± 6.79
	Weight (Kg)	61.00 ± 10.23
Medical history	Hypertension	21(70%)
	Diabetes	9(30%)
	Hyperlipidemia	7(23%)
	Hypoproteinemia,	4(13%)
	Anemia	4(13%)
	Atrial fibrillation	3(10%)
	Cerebrovascular disease	1(3%)
	Coronary heart disease	16(53%)
Operating history	CSI	3(10%)
	AVR	5(16%)
Cardiac function classification	NYHA II	3(10%)
	NYHA III	24(80%)
	NYHA IV	3(10%)
Others	CREA (umol/L)	74.23 ± 19.18
	eGFR (ml/min/1.73 m^2)	77.53 ± 17.35
	STS score (average,%)	3.13 ± 2.10

Note: BMI, Body Mass Index; CSI, coronary stent implantation; AVR, aortic valve replacemen; NYHA, New York Heart Association; CREA, creatinine; eGFR, estimated glomerular filtration rate; STS, Society of Thoracic Surgeons

Table 2 The aortic characteristics of the included patients

Project		In mm
CT three-dimensional imaging	Average annulus perimeter of aortic valve	72.51 ± 9.42
	Average annulus diameter	23.34 ± 3.43
Average coronary artery opening height	LCA	9.27 ± 4.12
	RCA	11.21 ± 3.45
Average diameter of valsalva	Left	29.12 ± 6.12
	Right	28.32 ± 6.34
	Non	29.46 ± 7.34
Aortic annulus area	All trilobal valves (area/mm^2)	412.00 ± 118.32

Note: LCA, Left coronary artery; RCA, Right coronary artery

Collection of clinic data

The clinical information collected included patients characteristics, cardiac function (NYHA classification) [20], creatinine, glomerular filtration rate, American Association of Thoracic Surgeons score [21]. Pre operative diameter, perimeter, area of the aortic valve annulus, height of the coronary artery opening, and operation time, length of hospital stay, postoperative adverse events and laboratory test indicators were collected.

Table 3 Coronary opening height and sinus of Valsalva of the included patients

Project	Size (mm)	Left (*N*=30)	Right (*N*=30)
Coronary opening height	≤ 10	25 (83%)	12 (40%)
	≤ 5	3(10%)	2(6%)
	5< x ≤ 8	6(20%)	3(10%)
	8< x ≤ 10	16(53%)	7(24%)
	>10	5(17%)	18(60%)
Sinus of Valsalva	≤ 25	5(17%)	10(33%)
	25< x ≤ 30	12(40%)	10(33%)
	30< x ≤ 35	9(30%)	7(24%)
	>35	4(13%)	3(10%)

Statistical analysis

All data in this study were analysed statistically using SPSS 26.0 software (Armonk, NY, USA). the continuous data was test with normal distribution and represented as mean ± SD and tested using the *t*-test. Count data were expressed as raw counts and percentages and tested using the X^2 test or Fisher's exact test. The t test was used with significance of $p < 0.05$.

Results

Selected data

A total of 30 patients (100%) were enrolled, with an average age of 72.00 ± 3.20 years. For details of the general clinical data and medical history characteristics of the included patients, see Table 1; the valve measurement characteristics are presented in Tables 2 and 3.

Intraoperative and postoperative results

The J-Valve was successfully implanted in all 30 patients. As a result of hemodynamic instability caused by severe heart failure or arrhythmia, two patients required cardiopulmonary bypass assistance during the operation. Five patients received preoperative coronary artery protection: 3 patients (10%) with coronary artery openings (height ≤ 5 mm) had a guidewire implanted in the coronary artery openings to monitor blood flow during the operation; 2 patients had stent stenosis (< 50%) with coronary artery openings < 8 mm after stent implantation. These patients underwent balloon dilation in the coronary stent and had a guidewire left in place to monitor coronary blood flow during the operation. Postoperatively, coronary blood flow was monitored and found to be TIMI 3 in all five patients, with no stenosis or obstruction detected, and coronary stent implantation was not required. All patients underwent balloon postdilatation during the operation. A 23-mm valve was predominantly implanted in 18 patients (60%), with fewer patients receiving valves of 21 (3.10%), 25 (7.24%) or 27 (2.6%) mm. Details are shown in Table 4. There were no instances of cerebrovascular accidents or moderate or

Table 4 Intraoperative and postoperative general situation of patients based on VARC-2 guideline

Project	*N*=30
Intraoperative CPB	2(6.7%)
Preoperative coronary protection	5(17%)
Average operation time (h)	4.11 ± 2.31
Coronary stent stenosis	2(6.7%)
Haemorrhage	0(0%)
ICU stay (d)	1.85 ± 1.24
CRRT	0(0%)
Permanent pacemaker implantation	3(10%)
Cerebrovascular events	0(0%)
Paravalvular leakage	0(0%)
All-cause death	0(0%)
Third degree atrioventricular block	3(10%)
Mortality rate	0(0%)

Note: CPB, cardiopulmonary bypass; ICU, Intensive care unit; CRRT, continuous renal replacement therapy

Table 5 Comparison of preoperative and postoperative 24-hour myocardial injury detection [mean ± SD, n(%)]

Project	Preoperative	Postoperative	*P* value
BNP	632.22 ± 141.37	423.91 ± 94.79	0.72
CRP	12.60 ± 2.82	40.47 ± 9.05	0.08
TNI	24.73 ± 5.53	2280.62 ± 509.96	0.12
MYO	8.90 ± 2.00	345.48 ± 77.25	0.03

Note: BNP, B-type sodium peptide; CRP, C-reactive protein; TNI, Troponin I; MYO, myoglobin. $P<0.05$

Table 6 Comparison of preoperative and postoperative 30 day echocardiography [mean ± SD, case(%)]

Project	Preoperative	Postoperative 30 days	*P* value
Left ventricle	49.00 ± 4.91	45.55 ± 5.47	0.09
left atrium	53.40 ± 8.20	40.50 ± 4.86	0.00
Ejection fraction	60.70 ± 8.20	57.80 ± 6.81	0.23

$P<0.05$

severe perivalvular leakage postoperatively. No patients died within 30 days of discharge.

Laboratory tests for myocardial injury, including BNP, CRP and TNI, conducted before and 24 h after the operation, revealed no statistically significant differences ($P>0.05$) (Table 5). Most patients were classified as NYHA grade III preoperatively, but at the 30-day postoperative follow-up, all patients were classified as grade I or II, with no patients classified as grade III or IV (Table 6). Postoperatively, patients experienced significant symptom relief, with no reports of chest tightness or chest pain, and their activity tolerance improved markedly compared with preoperative levels.

Discussion

In this study, the data of 30 patients with AS and low coronary artery openings treated using the J-Valve were analysed. The results showed that all patients recovered well postoperatively, with no deaths within 30 days. During the hospitalisation period, there were no instances of severe bleeding, cerebrovascular events or major perivalvular leakage. Myocardial injury lab tests detected no significant changes, and all patients demonstrated significant improvement in cardiac function and symptom relief. This indicates that J-Valve implantation is a safe and effective method for patients with low coronary openings.

Since the first successful TAVI treatment for patients with AS in 2002, various TAVI valves have been developed, categorised into self-expanding and balloon-expanding types. Different types of valves have different rates of coronary artery obstruction, with balloon-expanding valves having a higher incidence rate than self-expandable valves (0.81% vs. 0.34%) [12]. Since 2017, most valves available in China have been self-expanding, including the J-Valve and Venus-A valves. The J-Valve (Fig. 1) is characterised by three positioning parts (Fig. 2) and can be delivered via an apical approach using a thicker, shorter delivery device that is easier to manoeuvre. With the unique structural design of its locators (Fig. 3), the J-Valve may offer distinct advantages in treating patients with AS and low coronary artery openings [17].

The three positioning pieces of the J-Valve are placed in the three sinuses, protecting the coronary artery opening from becoming blocked by the biological valve leaflets. Among the patients in this study, five had a minimum left coronary artery opening height of 3.5 mm, and none experienced coronary artery stenosis or occlusion after the TAVI procedure. Three patients had coronary stents before the operation. As the indication for TAVI expands to younger and lower-risk individuals, future coronary intervention treatments may be necessary. Therefore, the short-frame TAVI valve (the J-Valve) appears more appropriate for these patients.

Coronary artery occlusion is a serious complication in TAVI, and although its risk is relatively low (less than 1%), certain patients remain at risk [12]. It is reported that the incidence of coronary artery occlusion in the damaged valve after aortic valve replacement is as high as 2.3%, with a 30-day mortality rate of up to 50% [12]. The incidence of coronary artery occlusion increases 3–4 times after a failed TAVI implantation via the catheter aortic valve [22]. The bicuspid aortic valve may lead to abnormal coronary artery configurations, especially in patients with separate openings of the left main artery and circumflex artery [12, 23, 24]. If patients with coronary artery occlusion do not receive timely and successful percutaneous coronary intervention or coronary artery bypass grafting, the mortality rate can reach 100% [12, 25, 26].

Fig. 1 J-Valve ™ system: Valve and delivery device

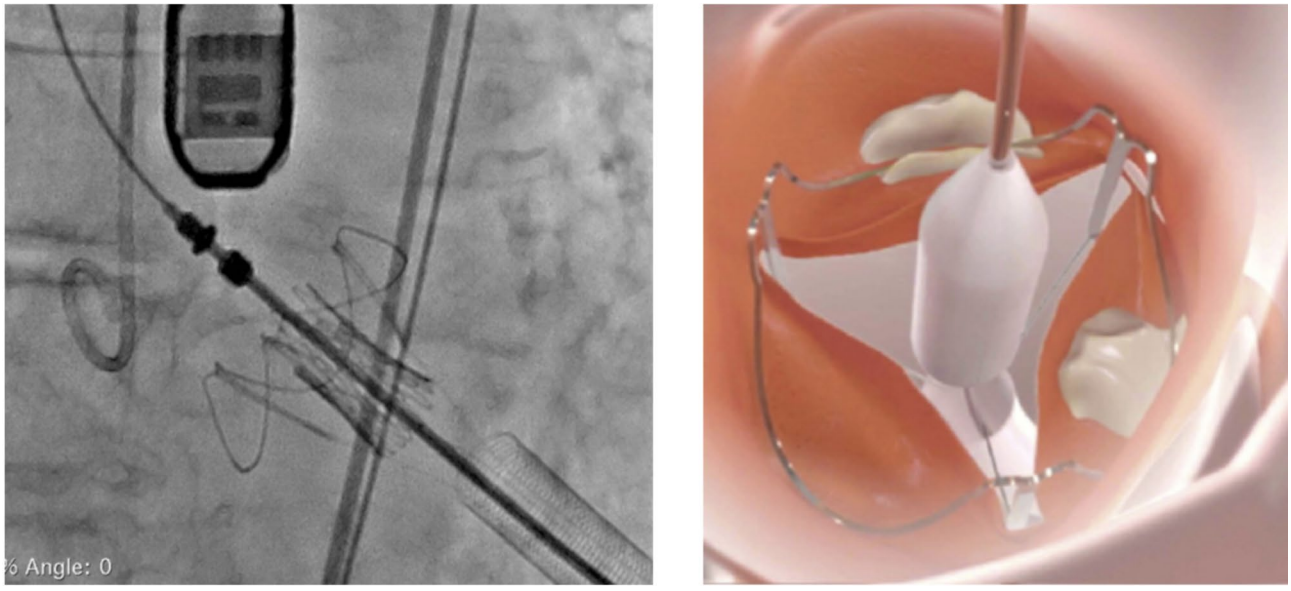

Fig. 2 J-Valve ™ system: Three U-shaped positioning parts. Angiography may be used to confirm positioning parts and valve positions

Accurately predicting coronary artery occlusion is challenging. Some predictors include the distance between the coronary orifice and valve annulus being less than 10 mm, the diameter of the Valsalva sinus being less than 28 mm and the height of the sinus junction being less than 15 mm [27–29]. Known risk factors are being a woman, a coronary opening height of <10 mm (or 12 mm in some studies), a width of the aortic sinus of <30 mm and a distance between the prosthetic valve and the coronary sinus opening of <4 mm after biological valve replacement (especially with wrapped or stentless prosthetic valves) [30, 31]. However, delayed coronary occlusion is a more dangerous complication, with a very low reporting rate.

This study found that the J-Valve locators effectively protected the coronary arteries in patients with AS and coronary artery openings of ≤10 mm. Early postoperative results revealed no coronary artery obstruction. Transthoracic echocardiography demonstrated good valve function, no coronary-related myocardial ischemia at discharge or 30-day follow-up and only mild perivalvular leakage. The skirt design of the J-Valve may reduce the probability of paravalvular leakage, and its three U-shaped positioning parts help minimise coronary opening obstruction.

The incidence of permanent pacemaker implants postoperatively was much lower than that associated with other valves, likely due to the J-Valve's special design [31, 32]. The three U-shaped locators in the sinuses prevent

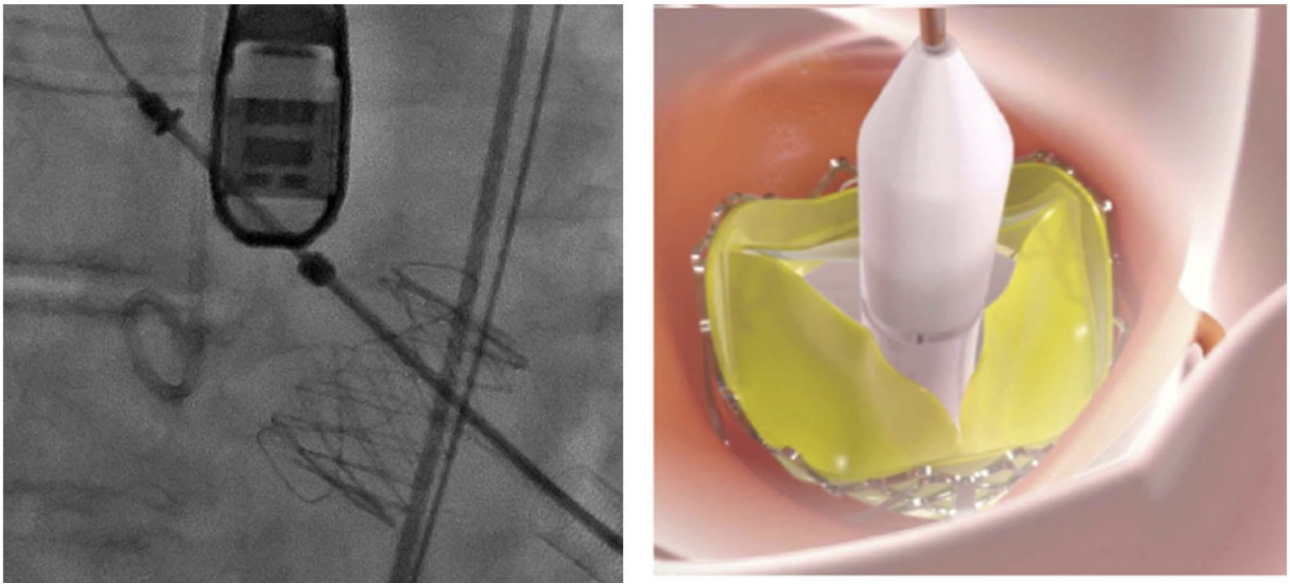

Fig. 3 Final release of the valve

the valve from diving deep into the ventricle, which is strongly related to the conduction block.

In this study, no patient died within 30 days postoperatively, a rate lower than that reported in many TA-TAVI studies [12]. This may be attributed to the low incidence of postoperative adverse events and the absence of serious cerebrovascular and cardiovascular complications. As shown in this study, there were no significant changes in left ventricular myocardial thickness and left ventricular ejection fraction ($P>0.05$).

This study indicates that patients with AS and low coronary openings who underwent TA-TAVI using the J-Valve can recover well perioperatively. However, a careful evaluation of the three-dimensional CT imaging of the aortic valve root is recommended to predict the probability of coronary artery occlusion. For patients at high risk of coronary artery occlusion, coronary artery protection therapy – either with a wire and catheter placed in the coronary artery or by selecting the J-Valve with its coronary artery protection function – should be considered.

Given that this study is a retrospective analysis with a short observation period and a small sample size, there may be selection bias. Additionally, no control cases were included for comparison. Despite the satisfactory results, a multi-centre prospective study with a larger sample size and longer follow-up is needed to verify the safety and efficacy of TA-TAVI using the J-Valve in high-risk patients with AS and low coronary artery openings.

Conclusion

Transapical TAVI using the J-Valve is technically feasible for patients with AS and low coronary artery openings, showing good postoperative safety and efficacy. The special positioning mechanism of the J-Valve with a short stent appears to provide coronary protection. However, further multi-centre clinical research is needed to evaluate the long-term complications and durability of the valve.

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N/A.

Author contributions
Xu QH and Zhang HB conceived of the study, and Wang SX, Li YH, Shen JL, Wu KS and Zhou JW participated in its design and data analysis and statistics and Xu QH helped to draft the manuscript. All authors read and approved the final manuscript.

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Data availability
All data generated or analysed during this study are included in this article. Further enquiries can be directed to the correspingding author.

Declarations

Ethics approval and consent to participate
This study was conducted in accordance with the Declaration of Helsinki and approved by the ethics committee of Mudanjiang Cardiovascular Disease Hospital, approval number (Medical Ethics Approval – 2022-32). Written informed consent was obtained from all participants.

Consent for publication
Not applicable.

Competing interests
The authors declare no competing interests.

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