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Comparison of therapeutic effects of transcatheter aortic valve replacement surgery on patients with severe aortic valve stenosis with different ejection fractions

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Abstract: Objective To investigate the efficacy of transcatheter aortic valve replacement (TAVR) in treating patients with severe aortic stenosis (AS) of different levels of cardiac function. **Methods** A retrospective analysis was conducted on clinical data of 72 patients who underwent TAVR for severe AS at the Xinjiang Uygur Autonomous Region People's Hospital from September 2016 to July 2022. Patients with a left ventricular ejection fraction (LVEF) ≥50% were included in the preserved ejection fraction group (Group A, *n*=44), while those with LVEF <50% were included in the reduced ejection fraction group (Group B, *n*=28). The effective orifice area (EOA), mean transvalvular pressure gradient (mPG), and LVR were observed in both groups preoperatively and postoperatively at 1 day, 3 months, and 12 months. The 6-minute walk test distance (6-MWT) was measured preoperatively and postoperatively at 3 months and 12 months for both groups. All patients were followed up to one year postoperatively to observe the readmission rate due to heart failure. **Results** Both groups showed significant improvement in EOA and mPG on the first postoperative day, which remained stable thereafter. On the first postoperative day, left ventricular remodeling indicators [left ventricular end-diastolic diameter (LVEDD), left ventricular end-systolic diameter (LVESD), left ventricular posterior wall thickness (LVPWT), LVEF] improved significantly in both groups compared to preoperative values (P<0.05). During subsequent follow-ups, Group A maintained a relatively stable state, while Group B continued to show left ventricular remodeling (LVR) until the end of the follow-up period. The 6-MWT at 3 months postoperatively improved significantly in both groups compared to preoperative values and remained stable thereafter. The readmission rate due to heart failure within one year between Group A and Group B showed no statistically significant difference (4.54% *vs* 21.43%, χ^2=3.380, P<0.05). **Conclusion** TAVR can effectively alleviate obstruction of the left ventricular outflow tract in patients with severe AS and different ejection fractions, improve exercise tolerance, and promote left ventricular reverse remodeling. For patients with preserved ejection fraction and severe AS, intervention should be carried out as early as possible.

Keywords: Aortic stenosis; Transcatheter aortic valve replacement; Transcatheter interventional treatment; Ventricular remodeling; Heart failure

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Aortic stenosis (AS) is a common cardiovascular disease in the elderly population, with an incidence rate only lower than hypertension and coronary heart disease, and it increases with age. Severe AS patients often have significant left ventricle remodeling (LVR) and varying degrees of cardiac dysfunction [1-2]. Once patients develop symptoms, if no surgical intervention is performed, their 5-year survival rate is only 32% [3]. Currently, transcatheter aortic valve replacement (TAVR) has become one of the main treatments for severe AS patients, with significant effects [4]. However, there are few reports on the comparison of the therapeutic effects of TAVR in severe AS patients with different cardiac functions in China. This study summarized the clinical data of severe AS patients treated with TAVR in Xinjiang Uygur Autonomous Region People's Hospital since 2016 and analyzed the therapeutic effects of TAVR in severe AS patients with different cardiac functions.

1 Materials and Methods

1.1 General Information

A retrospectively analysis of the clinical data of 72 severe AS patients who underwent TAVR treatment in Xinjiang Uygur Autonomous Region People's Hospital from June 2016 to July 2022 was conducted. Based on the patient's condition, AS patients with left ventricular ejection fraction (LVEF) ≥ 50% were included in the preserved ejection fraction group (Group A, *n*=44), and AS patients with LVEF < 50% were included in the reduced ejection fraction group (Group B, *n*=28).

Inclusion criteria:

(1) Symptomatic AS patients (symptoms caused by AS), with an effective orifice area (EOA) ≤ 1.0 cm^2, mean transvalvular pressure gradient (mPG) ≥ 40

mmHg, and mean aortic valve transvalvular blood flow velocity ≥ 4.0 m/s;

(2) Cardiac function grade ≥ II (NYHA classification);

(3) Age ≥ 60 years;

(4) Expected lifespan ≥ 1 year.

Exclusion criteria:

(1) Expected lifespan < 1 year;

(2) Untreated severe coronary artery disease;

(3) Left ventricular thrombus;

(4) Myocardial infarction within 30 days;

(5) Aortic anatomic morphology unsuitable for TAVR (aortic root dilation > 55 mm, aortic root dilation > 45 mm with aortic dissection);

(6) LVEF < 20%;

(7) Severe right ventricular dysfunction;

(8) Complications such as hypertrophic cardiomyopathy with left ventricular outflow obstruction.

All patients received optimized drug treatment after admission and underwent TAVR treatment after multidisciplinary consultation. This study was approved by the Ethics Committee of the People's Hospital (approval number: KY2021031904), and all patients signed informed consent forms.

1.2 Surgical Methods

All patients undergoing TAVR surgery were prophylactically treated with antibiotics and received intravenous combined general anesthesia. Guided by digital subtraction angiography (DSA) and transesophageal echocardiography, a temporary pacemaker was implanted through the internal jugular vein. Routine bilateral femoral artery puncture was performed under ultrasound guidance (for those who needed coronary artery protection, routine puncture of the right radial artery was also performed). A vascular suture device was pre-embedded in the main path, and a guiding sheath was advanced above the abdominal aorta. A pigtail catheter was placed in the auxiliary path for supravalvular angiography. Usually, a 6F Amplatz-L left coronary angiography catheter was used as the guiding catheter, and a straight-tipped super-slip guidewire was used to cross the valve. The pigtail catheter was then exchanged to measure the transvalvular pressure gradient, followed by the exchange of a super-hard guidewire. Routine pre-dilation was performed using a 16-20 mm balloon, and the valve delivery system was introduced. The auxiliary pigtail catheter was placed in the non-coronary sinus, with its lowest point serving as a reference line for the annulus. The optimal release position was set at 0-4 mm below the aortic annulus. After release, the valve delivery system was withdrawn, the femoral artery was sutured, and the patient was transferred to the CCU for monitoring and routine antibiotic use for 72 hours.

1.3 Observation Indicators

The EOA, mPG, and LVR indices were observed in both groups of patients before TAVR surgery and at 1 day, 3 months, and 12 months postoperatively. The 6-minute walk test distance (6-MWD) was measured in both groups before surgery and at 3 months and 12 months postoperatively. All patients were followed up for 1 year postoperatively to observe rehospitalization due to heart failure. For the LVR indices, echocardiography was performed using a Vivid E9 (GE Company). Left ventricular end-diastolic diameter (LVEDD), left ventricular end-systolic diameter (LVESD), and left ventricular posterior wall thickness (LVPWT) were measured using two-dimensional images in the left ventricular long-axis view. LVEF and EOA were measured using a biplane method in the four-chamber view. Mean transvalvular pressure gradient was calculated using continuous Doppler measurements of aortic valve blood flow velocity and time-velocity integral, and EOA was calculated using the continuity equation method.

1.4 Statistical Analysis

Statistical analysis was performed using SPSS 25.0 software. Normally distributed continuous variables were expressed as $\bar{x} \pm s$. Repeated measures analysis of variance was used for comparison between two groups at multiple time points, and pairwise comparison was performed using the LSD-*t* test. Categorical variables were expressed as counts, and group comparisons were performed using the chi-square test or Fisher's exact test. $P<0.05$ was considered statistically significant.

2 Results

2.1 Baseline data

The level of N-terminal pro B-type natriuretic peptide (NT-proBNP) in Group B was higher than that in Group A, and the difference was statistically significant ($P<0.05$). There was no statistically significant difference in other data between the two groups ($P>0.05$) [**Tab.1**].

2.2 Follow-up results

Seventy-two patients were followed up postoperatively, and all patients were followed up for one year after surgery. During the follow-up, 2 patients in Group A and 6 patients in Group B were hospitalized due to acute cardiac insufficiency and discharged after improvement with medication. There was no statistically significant difference in the one-year rehospitalization rate of heart failure between the two groups (4.54% *vs* 21.43%, $\chi^2=3.380$, $P=0.066$).

2.2.1 Comparison of 6-MWD

Both groups showed an increasing trend in 6-MWD distance over time ($P<0.01$), and there was no interaction effect between group and time (P>0.05) [**Tab.2**].

2.2.2 Comparison of EOA and mPG

Both EOA and mPG in the two groups showed an improvement trend over time (P<0.01), but neither of them showed interaction effect between group and time (P>0.05) [**Tab.3**].

Tab.1 Comparison of baseline data between two groups of patients

Indicators	Group A (n=44)	Group B (n=28)	t/χ^2 Value	P Value
Age (years, $\bar{x}\pm s$)	72.07±7.30	71.61±4.02	0.345	0.731
Male (cases)	33	16	2.510	0.128
BMI (kg/m^2, $\bar{x}\pm s$)	23.34±2.96	23.11±2.88	0.330	0.741
NYHA grade (cases)				
II	22	14		
III	20	10	2.340	0.311
IV	2	4		
NT-proBNP (ng/L, $\bar{x}\pm s$)	11,096.32±206.07	11,699.32±385.06	7.621	<0.001
STS grade (cases)				
4%-8%	4	4		0.703[a]
>8%	40	24		
Bicuspid aortic (cases)				
Type 0	8	2		
Type 1	20	13		0.748[a]
Type 2	2	1		
Complication (cases)				
Hypertension	15	8	0.240	0.796
Diabetes	18	10	0.194	0.805
Atrial fibrillation	9	4		0.754[a]
Coronary abnormalities (cases)				
Coronary atherosclerosis	28	16	0.304	0.626
Coronary heart disease	16	12		

Note: [a] meant Fisher's exact probability method.

Tab.2 Comparison of two groups of 6-WMD (m, $\bar{x}\pm s$)

Group	Before surgery	3 months after surgery	1 year after surgery
Group A (n=44)	198.86±14.18	445.11±26.45[a]	447.05±26.29[a]
Group B (n=28)	198.93±19.88	436.25±36.07[a]	439.29±36.41[a]
F_{time}/P_{time} Value		1668.995/<0.001	
F_{group}/P_{group} Value		1.174/0.282	
$F_{interation}/P_{interation}$ Value		1.110/0.333	

Note: Compared with same group before the surgery, [a]P<0.05.

2.2.3 Comparison of LVR indicators between the two groups

Both groups showed an improvement trend in LVR indicators over time (P<0.01), and there was an interaction effect between group and time (P<0.01) [**Tab.3**].

3 Discussion

Severe AS patients are often accompanied by left ventricular dysfunction. With the progress of the disease, pathological changes often occur in myocardial cells, namely decompensated remodeling. Even if some patients receive TAVR treatment, LVR cannot be improved, and the prognosis is often poor [5-6]. The *2021 ESC/EACTS Guidelines for the Management of Valvular Heart Disease* pointed out that for symptomatic severe AS patients, surgical intervention should be performed as soon as possible to improve their prognosis [7].

The results of this study showed that the baseline NT-proBNP level and the rate of rehospitalization for heart failure within one year after surgery in Group B were higher than those in Group A, indicating that compared with AS patients with preserved ejection fraction, the condition of AS patients with reduced ejection fraction is more severe, and their cardiac function and prognosis are poorer, which is consistent with the results of relevant studies [8-9]. The 6-WMD of both groups showed a trend of prolongation over time, and the change trends were similar. The 6-WMD

Tab.3 Two sets of cardiac ultrasound results($\bar{x}\pm s$)

Group	EOA (cm^2)				mPG (mmHg)			
	Before surgery	1 day after surgery	3 months after surgery	1 year after surgery	Before surgery	1 day after surgery	3 months after surgery	1 year after surgery
Group A (n=44)	0.60±0.14	1.75±0.19[a]	1.76±0.19[a]	1.79±0.17[a]	66.05±15.29	5.55±2.29[a]	5.55±2.69	5.23±2.48
Group B (n=28)	0.65±0.15	1.64±0.25[a]	1.66±0.22[a]	1.71±0.22[a]	68.21±15.09	4.89±2.30[a]	4.61±2.08	4.32±1.85
F_{time}/P_{time} Value	472.682/<0.001				372.389/<0.001			
F_{group}/P_{group} Value	2.153/0.147				0.007/0.935			
$F_{interation}/P_{interation}$ Value	2.100/0.108				1.124/0.346			
Group	**LVPWT (mm)**				**LVEF (%)**			
	Before surgery	1 day after surgery	3 months after surgery	1 year after surgery	Before surgery	1 day after surgery	3 months after surgery	1 year after surgery
Group A (n=44)	12.34±1.18	11.16±1.01[a]	11.00±0.84	10.91±0.77	53.66±2.87	55.45±2.50	56.07±2.30	56.73±2.32
Group B (n=28)	13.04±0.84	12.07±0.54[a]	11.25±0.65[ab]	10.39±0.57[abc]	43.85±3.18d	45.64±2.83d	49.32±2.76[abd]	54.29±2.73[abc]
F_{time}/P_{time} Value	1668.995/<0.001				178.304/<0.001			
F_{group}/P_{group} Value	1.174/0.282				151.091/<0.001			
$F_{interation}/P_{interation}$ Value	1.110/0.333				101.283/<0.001			
Group	**LVEDD (mm)**				**LVESD (mm)**			
	Before surgery	1 day after surgery	3 months after surgery	1 year after surgery	Before surgery	1 day after surgery	3 months after surgery	1 year after surgery
Group A (n=44)	61.93±8.00	52.55±7.65[a]	50.27±7.43	49.59±6.84	43.57±4.32	40.32±4.31[a]	38.93±3.98[ab]	37.70±3.66
Group B (n=28)	62.21±8.50	54.46±6.84[a]	49.79±6.09	46.64±4.40	42.18±4.75	39.43±3.86[a]	36.89±2.25[ab]	34.71±2.65[abcd]
F_{time}/P_{time} Value	777.707/<0.001				124.775/<0.001			
F_{group}/P_{group} Value	0.036/0.851				4.307/0.042d			
$F_{interation}/P_{interation}$ Value	22.88/<0.001				5.522/0.002			

Note: Compared with preoperative group, [a]P<0.05; compared with postoperative day 1, [b]P<0.05; compared with postoperative month 3, [c]P<0.05; compared with Group A, [d]P<0.05.

at 3 months after surgery was significantly improved compared with that before surgery, and then remained stable. This indicates that the exercise tolerance of severe AS patients can be significantly improved after TAVR, and the first three months after surgery may be a critical period for the recovery of exercise tolerance, but the factors affecting its recovery have not been further explored. Both groups of patients showed a trend of changes in EOA and mPG over time, and the changes can be divided into two stages. The first stage is from before surgery to 1 day after surgery, during which the EOA and mPG of both groups were significantly improved. The second stage is from 1 day after surgery to 12 months after surgery, during which the EOA and mPG of both groups remained relatively stable. This indicates that TAVR can effectively relieve the stenosis of the valve in severe AS patients, eliminate the outflow obstruction, and the effect is stable [10-11]. The LVR indicators (LVEF, LVPWT, LVEDD, LVESD) of both groups also showed a trend of changes over time. Group A can be divided into two stages. The first stage is from before surgery to 1 day after surgery, during which the above indicators were significantly improved. The second stage is from 1 day after surgery to 1 year after surgery, during which the LVR indicators remained relatively stable. The LVR of patients in Group B began to improve from 1 day after surgery and continued until 1 year after surgery. This indicates that it takes longer for AS patients with reduced ejection fraction to achieve left ventricular reverse remodeling after TAVR, which also indirectly indicates that with the decrease of LVEF, the pathological changes of LVR and left ventricular structure will be more significant [12].

This study has the following limitations: it was a single-center study; No further follow-up of the LVR indicators in Group B, and their LVR indicators may further improve over time; No long-term follow-up of the patients' heart function grades; No analysis of the factors affecting the recovery of exercise tolerance after TAVR.

In summary, TAVR can effectively relieve the left ventricular outflow obstruction, improve exercise tolerance, and promote LVR in severe AS patients with different ejection fractions. For AS patients with preserved ejection fraction, intervention should be performed as soon as possible to avoid deterioration of cardiac function, excessive left ventricular remodeling, and poor prognosis due to disease progression.

Conflict of Interest None

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·论　著·

经导管主动脉瓣置换术对不同射血分数重度主动脉瓣狭窄患者的疗效比较

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摘要：目的　探讨经导管主动脉瓣置换术(TAVR)治疗不同心功能重度主动脉瓣狭窄(AS)患者的疗效。**方法**　回顾性分析2016年9月至2022年7月在新疆维吾尔自治区人民医院72例行TAVR的重度AS患者的临床资料。将左心室射血分数(LVEF)≥50%的重度AS患者纳入射血分数保留组(A组，$n=44$)，将LVEF<50%的重度AS患者纳入射血分数降低组(B组，$n=28$)。观察两组患者TAVR术前及术后1天、3个月、12个月的有效瓣口面积(EOA)、平均跨瓣压差、左心室重构(LVR)指标；两组患者TAVR术前及术后3个月、12个月的6分钟步行实验距离(6-MWD)；所有患者均随访至术后1年，观察心力衰竭(心衰)再住院情况。**结果**　两组患者术后1天的EOA、平均跨瓣压差均较术前显著改善，之后保持稳定；术后第1天，两组患者的LVR指标[左心室舒张末期内径(LVEDD)、左心室收缩末期内径(LVESD)、左心室后壁厚度(LVPWT)、LVEF]均较术前明显改善($P<0.05$)。在随访过程中，A组患者LVR指标保持相对稳定，B组患者的LVR指标改善则持续至随访结束；两组患者术后3个月的6-MWD均较术前显著改善，之后均保持稳定；A组和B组1年内心衰再住院率比较，差异无统计学意义(4.54% *vs* 21.43%，$\chi^2=3.380$，$P=0.066$)。**结论**　TAVR可有效解除不同射血分数重度AS患者左心室流出道的梗阻、提高活动耐量、促进左心室逆重构，对于射血分数保留的重度AS患者应该尽早进行干预。

关键词： 主动脉瓣狭窄；经导管主动脉瓣置换术；经导管介入治疗；心室重构；心力衰竭

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Comparison of therapeutic effects of transcatheter aortic valve replacement surgery on patients with severe aortic valve stenosis with different ejection fractions

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Abstract: Objective　To investigate the efficacy of transcatheter aortic valve replacement (TAVR) in treating patients with severe aortic stenosis (AS) of different levels of cardiac function. **Methods**　A retrospective analysis was conducted on clinical data of 72 patients who underwent TAVR for severe AS at the Xinjiang Uygur Autonomous Region People's Hospital from September 2016 to July 2022. Patients with a left ventricular ejection fraction (LVEF) ≥50% were included in the preserved ejection fraction group (group A, $n=44$), while those with LVEF<50% were included in the reduced ejection fraction group (group B, $n=28$). The effective orifice area (EOA), mean transvalvular pressure gradient, and left ventricular remodeling (LVR) were observed in both groups preoperatively and postoperatively at 1 day, 3 months, and 12 months. The 6-minute walk distance (6-MWD) was measured preoperatively and postoperatively at 3 months and 12 months for both groups. All patients were followed up to one year postoperatively to observe the readmission rate due to heart failure. **Results**　Both groups showed significant improvement in EOA and mean transvalvular pressure gradient on the first postoperative day, which remained stable thereafter. On the first postoperative

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day, LVR indicators [left ventricular end-diastolic diameter (LVEDD), left ventricular end-systolic diameter (LVESD), left ventricular posterior wall thickness (LVPWT), LVEF] improved significantly in both groups compared to preoperative values (P<0.05). During subsequent follow-ups, group A maintained a relatively stable state, while group B continued to show LVR until the end of the follow-up period. The 6-MWD at 3 months postoperatively improved significantly in both groups compared to preoperative values and remained stable thereafter. The readmission rate due to heart failure within one year between group A and group B showed no statistically significant difference (4.54% *vs* 21.43%, χ^2 = 3.380, P = 0.066). **Conclusion** TAVR can effectively alleviate obstruction of the left ventricular outflow tract in patients with severe AS and different ejection fractions, improve exercise tolerance, and promote left ventricular reverse remodeling. For patients with preserved ejection fraction and severe AS, intervention should be carried out as early as possible.

Keywords: Aortic stenosis; Transcatheter aortic valve replacement; Transcatheter interventional treatment; Ventricular remodeling; Heart failure

Fund program: Key Research and Development Plan Project of Xinjiang Uygur Autonomous Region (2022B03009-3)

主动脉瓣狭窄(aortic stenosis, AS)是老年人群较常见的心血管疾病,其发病率仅低于高血压及冠心病,且随年龄增长而增加。重度 AS 患者常合并显著的左心室重构(left ventricle remodel, LVR)及不同程度的心功能不全[1-2],患者一旦出现症状,若不进行手术干预,其 5 年生存率仅 32%[3]。目前,经导管主动脉瓣置换术(transcatheter aortic valve replacement, TAVR)已成为治疗重度 AS 患者的主要手段之一,效果显著[4],但对不同心功能重度 AS 患者 TAVR 术后疗效的比较国内鲜有报道。本研究分析不同心功能重度 AS 患者 TAVR 术后的治疗效果。

1　资料与方法

1.1　一般资料　回顾性分析 2016 年 6 月至 2022 年 7 月于新疆维吾尔自治区人民医院行 TAVR 治疗的重度 AS 患者的临床资料,共 72 例。根据患者病情,将左室射血分数(left ventricular ejection fraction, LVEF)≥50%的 AS 患者纳入射血分数保留组(A 组, n=44),将 LVEF<50%的 AS 患者纳入射血分数降低组(B 组, n=28)。纳入标准:(1) 症状性 AS 患者(症状为 AS 所致),有效瓣口面积(effective orifice area, EOA)≤1.0 cm^2,平均跨瓣压差≥40 mmHg,主动脉瓣平均跨瓣血流速度≥4.0 m/s;(2) 美国纽约心脏病学会(New York Heart Association, NYHA)心功能分级≥Ⅱ级;(3) 年龄≥60 岁;(4) 预期寿命≥1 年。排除标准:(1) 预期寿命<1 年;(2) 合并未经处理的严重冠状动脉(冠脉)病变;(3) 左心室血栓;(4) 30 d 内的心肌梗死;(5) 主动脉解剖形态不适合 TAVR(主动脉根部扩张>55 mm 或主动脉根部扩张>45 mm 合并主动脉夹层);(6) LVEF<20%;(7) 严重右心功能不全;(8) 合并肥厚性心肌病伴左室流出道梗阻等。所有患者入院后均接受优化药物治疗,经多学科会诊后行 TAVR 治疗。本研究经新疆维吾尔自治区人民医院伦理委员会审核批准(批件号:KY2021031904),所有患者均签署知情同意书。

1.2　手术方法　所有 TAVR 手术患者术前均预防性使用抗生素,接受静脉复合全身麻醉。在数字减影血管造影(digital substraction angiography, DSA)、经食管心脏彩超等设备的引导下操作,经颈内静脉植入临时起搏器。超声引导下常规穿刺双侧股动脉(需冠状动脉保护者,常规穿刺右桡动脉),主路预埋血管缝合器,放置引导鞘管推进至腹主动脉以上,辅路放置猪尾导管行瓣上造影,通常以 6F Amplatz-L 左冠脉造影导管为指引导管,以直头超滑导丝跨瓣,交换猪尾导管测跨瓣压差,后交换超硬导丝,常规使用 16~20 mm 球囊进行预扩张,送入瓣膜输送系统,将辅路猪尾导管置于无冠窦,其最低点作为瓣环参考线,以主动脉瓣环下 0~4 mm 作为最佳释放位置,释放后退出瓣膜输送系统,缝合股动脉,转心血管重症监护室监护并常规使用抗生素 72 h。

1.3　观察指标　观察两组患者 TAVR 术前及术后 1 天、3 个月、12 个月的 EOA、平均跨瓣压差、LVR 指标;两组患者 TAVR 术前及术后 3 个月、12 个月的 6 分钟步行实验距离(6-minute walk distance, 6-MWD);所有患者均随访至术后 1 年,观察心衰再住院情况。LVR 指标:使用 Vivid E9(GE 公司)心脏彩超,取左室长轴位,采用二维图像,测量左心室舒张末期内径(left ventricular end-diastolic diameter, LVEDD),左心室收缩末期内径(left ventricular end-systolic diameter, LVESD)以及左心室的后壁厚度(left ventricular posterior wall thickness, LVPWT);取四腔心切面,应用双平面法,测量 LVEF、EOA、平均跨瓣压差;取五腔心切面,以连续多普勒测量主动脉瓣血流速度、时间速度积分,计算平均跨瓣压差,通过连续方程法计算 EOA。

1.4　统计学方法　采用 SPSS 25.0 软件进行统计学分析。符合正态分布的计量资料以 $\bar{x}\pm s$ 表示,多时点两组间比较采用重复测量设计的方差分析,两两比较采用 LSD-t 检验;计数资料以例表示,组间比较采用 χ^2 检验或 Fisher 确切概率法。$P<0.05$ 为差异有统计学意义。

2　结　果

2.1　两组基线资料比较　B 组 N-末端 B 型利钠肽原(N-terminal pro B-type natriuretic peptide, NT-proBNP)水平高于 A 组($P<0.05$)。两组其他资料比较,差异均无统计学意义($P>0.05$)。见表 1。

2.2　随访结果　对 72 例患者进行术后随访,均随访至术后 1 年。随访中,A 组有 2 例、B 组有 6 例患者因急性心衰入院,经药物治疗后好转出院,两组患者 1 年心衰再住院率比较,差异无统计学意义(4.54% *vs* 21.43%, $\chi^2=3.380$, $P=0.066$)。

2.2.1　6-MWD 比较　两组患者的 6-MWD 随时间推移均有延长的趋势($P<0.01$),分组与时间无交互效应($P>0.05$)。见表 2。

2.2.2　EOA 及平均跨瓣压差的比较　两组患者的 EOA 及平均跨瓣压差随时间推移均有改善($P<0.01$),分组与时间无交互效应($P>0.05$)。见表 3。

2.2.3　LVR 指标比较　两组患者 LVR 指标随时间推移均有改善($P<0.01$),LVEF、LVEDD、LVESD 分组与时间有交互效应($P<0.01$)。见表 3。

表 1　两组患者基线资料的比较

Tab. 1　Comparison of baseline data between two groups of patients

指标	A 组($n=44$)	B 组($n=28$)	t/χ^2 值	P 值
年龄(岁)[a]	72.07±7.30	71.61±4.02	0.345	0.731
男性(例)	33	16	2.510	0.128
BMI(kg/m^2)[a]	23.34±2.96	23.11±2.88	0.330	0.741
心功能 NYHA 分级(例)				
Ⅱ	22	14		
Ⅲ	20	10	2.340	0.311
Ⅳ	2	4		
NT-proBNP(ng/L)[a]	11 096.32±206.07	11 699.32±385.06	7.621	<0.001
坐站试验评分(例)				
4%~8%	4	4		0.703[b]
>8%	40	24		
二叶式瓣(例)[c]				
Type 0	8	2		
Type 1	20	13		0.748[b]
Type 2	2	1		
合并症(例)				
高血压	15	8	0.240	0.796
糖尿病	18	10	0.194	0.805
心房颤动	9	4		0.754[b]
冠脉异常(例)				
冠脉粥样硬化	28	16	0.304	0.626
冠心病	16	12		

注:BMI 为身体质量指数。[a] 表示数据形式为 $\bar{x}\pm s$;[b] 为 Fisher 确切概率法;[c] 为仅部分患者为二叶式瓣。

表 2　两组 6-WMD 比较　(m, $\bar{x}\pm s$)

Tab. 2　Comparison of two groups of 6-WMD　(m, $\bar{x}\pm s$)

组别	例数	术前	术后 3 个月	术后 1 年
A 组	44	198.86±14.18	445.11±26.45[a]	447.05±26.29[a]
B 组	28	198.93±19.88	436.25±36.07[a]	439.29±36.41[a]
$F_{时间}/P_{时间}$ 值			1 668.995/<0.001	
$F_{组间}/P_{组间}$ 值			1.174/0.282	
$F_{交互}/P_{交互}$ 值			1.110/0.333	

注:与本组术前比较,[a]$P<0.05$。

表 3　两组心脏超声结果　($\bar{x}\pm s$)

Tab. 3　Two sets of cardiac ultrasound results　($\bar{x}\pm s$)

组别	例数	EOA(cm^2)				平均跨瓣压差(mmHg)			
		术前	术后 1 天	术后 3 个月	术后 1 年	术前	术后 1 天	术后 3 个月	术后 1 年
A 组	44	0.60±0.14	1.75±0.19[a]	1.76±0.19[a]	1.79±0.17[a]	66.05±15.29	5.55±2.29[a]	5.55±2.69[a]	5.23±2.48[a]
B 组	28	0.65±0.15	1.64±0.25[a]	1.66±0.22[a]	1.71±0.22[a]	68.21±15.09	4.89±2.30[a]	4.61±2.08[a]	4.32±1.85[a]
$F_{时间}/P_{时间}$ 值		472.682/<0.001				372.389/<0.001			
$F_{组间}/P_{组间}$ 值		2.153/0.147				0.007/0.935			
$F_{交互}/P_{交互}$ 值		2.100/0.108				1.124/0.346			

组别	例数	LVPWT(mm)				LVEF(%)			
		术前	术后 1 天	术后 3 个月	术后 1 年	术前	术后 1 天	术后 3 个月	术后 1 年
A 组	44	12.34±1.18	11.16±1.01[a]	11.00±0.84[a]	10.91±0.77[a]	53.66±2.87	55.45±2.50[a]	56.07±2.30[a]	56.73±2.32[a]
B 组	28	13.04±0.84	12.07±0.54[a]	11.25±0.65[ab]	10.39±0.57[abc]	43.85±3.18[d]	45.64±2.83[ad]	49.32±2.76[abd]	54.29±2.73[abc]
$F_{时间}/P_{时间}$ 值		1 668.995/<0.001				178.304/<0.001			
$F_{组间}/P_{组间}$ 值		1.174/0.282				151.091/<0.001			
$F_{交互}/P_{交互}$ 值		1.110/0.333				101.283/<0.001			

组别	例数	LVEDD(mm)				LVESD(mm)			
		术前	术后 1 天	术后 3 个月	术后 1 年	术前	术后 1 天	术后 3 个月	术后 1 年
A 组	44	61.93±8.00	52.55±7.65[a]	50.27±7.43[a]	49.59±6.84[a]	43.57±4.32	40.32±4.31[a]	38.93±3.98[ab]	37.70±3.66[ab]
B 组	28	62.21±8.50	54.46±6.84[a]	49.79±6.09[a]	46.64±4.40[abcd]	42.18±4.75	39.43±3.86[a]	36.89±2.25[ab]	34.71±2.65[abcd]
$F_{时间}/P_{时间}$ 值		777.707/<0.001				124.775/<0.001			
$F_{组间}/P_{组间}$ 值		0.036/0.851				4.307/0.042			
$F_{交互}/P_{交互}$ 值		22.88/<0.001				5.522/0.002			

注:与本组术前比较,[a]$P<0.05$;与术后 1 天比较,[b]$P<0.05$;与术后 3 个月比较,[c]$P<0.05$;与 A 组比较,[d]$P<0.05$。

3 讨　论

重度 AS 患者常伴左心功能不全,随病程进展,心肌细胞常发生病理性改变,即失代偿性重构,部分患者即使接受 TAVR 治疗,LVR 也无法得到改善,预后往往较差[5-6]。《2021 ESC/EACTS 心脏瓣膜病管理指南》指出,对于症状型重度 AS 患者,应尽早进行手术干预,以改善其预后[7]。

本研究结果显示,B 组患者的基线 NT-proBNP 水平较 A 组更高,说明射血分数降低与射血分数保留的 AS 患者相比较,前者的病情更重,心功能及预后更差,与相关研究结果一致[8-9]。两组患者的6-WMD 随时间推移均有延长,且变化趋势相似,术后 3 个月的 6-WMD 均较术前明显改善,之后保持稳定,说明重度 AS 患者在 TAVR 术后,活动耐量可显著改善,术后 3 个月以内可能为其活动耐量恢复的关键时期。两组患者 EOA 及平均跨瓣压差均随时间有变化,其变化可分为两个阶段,阶段一是术前至术后 1 天,两组患者 EOA 及平均跨瓣压差均得到显著改善;阶段二是术后 1 天至术后 12 个月,两组患者的两项指标均保持相对稳定。说明 TAVR 可有效解除重度 AS 患者瓣膜的狭窄,解除流出道梗阻,且效果稳定[10-11]。两组 LVR 指标(LVEF、LVPWT、LVEDD、LVESD)亦随时间有变化,A 组可分为两个阶段,阶段一是术前至术后 1 天,上述指标显著改善;阶段二是术后 1 天至术后 1 年,LVR 指标保持相对稳定。B 组患者的 LVR 指标则从术后 1 天开始持续改善到术后 1 年。这说明射血分数降低的 AS 患者 TAVR 术后左心室逆重构所需的时间更长,也从侧面说明随患者 LVEF 降低,其 LVR 及左心室结构的病理性改变将更为显著[12]。

本研究有如下不足:单中心研究;未进一步对 B 组患者的 LVR 指标进行随访,其可能会随时间推移而进一步改善;未对患者的心功能分级进行长期随访;未分析影响患者 TAVR 术后活动耐量恢复的因素。

综上所述,TAVR 可有效解除不同射血分数重度 AS 患者左心室流出道梗阻、提高活动耐量、促进 LVR。对于射血分数保留的 AS 患者应尽早进行干预,避免出现因疾病进展而导致的心功能恶化、左心室过度重构、预后不佳。

利益冲突　无

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