بیمارستان قلب شهید رجایی

نتایج بیماران دارای دریچه دولتی آئورت که در طی سال های ۹۸-۸۲ در بیمارستان قلب و عروق شهید رجایی تحت درمان دارویی یا جراحی قرار گرفته اند

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هومن بخشنده آبکنار	همکار طرح	مشاوره و آنالیز آماری	
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پیمان طباطبایی	همکار طرح	جمع آوری نمونه ها	
مینا دانشمندی	همکار طرح	بررسی فرمها و ثبت مشخصات بیماران	

دانشکده/مرکز مربوطه

رده	نوع ارتباط با مرکز
مرکز تحقیقات بیماری های دریچه ای قلب	وارد کننده

متون پیشنهاد

آیتم اطلاعات تفضیلی	متن

جدول متغیرها

ردیف	عنوان متغیر	نوع متغیر		کمی		کیفی		تعریف علمی – عملی	نحوه اندازه گیری	مقیاس
		مستقل	وابسته	پیوسته	گسسته	اسمی	رتبه‌ای			
1	Age	*		*				The years of life	Examination	Year
2	Sex	*				*		Phenotype	Examination	Male/Female
3	Weight	*		*				Weight of body	Examination	Kg

Meter	Examination	Height of body				*		*	Height	4
Kg/m^2	Examination	Body mass index				*		*	Body mass index	5
Yes/No	Examination	Defined based on guidelines appropriate for age groups and it is mentioned in hospital database in echocardiographic evaluations		*				*	Congenital heart disease	6
Yes/No	Database	The surgical or interventional modalities used for BAV repair as well as the medical management of BAV cases		*				*	Type of BAV management	7
Yes/No	Database	Any surgeries performed concomitant with AV repair		*				*	Concomitant surgery	8
mm	Echocardiography	The size of thoracic aorta measured by echocardiography at baseline and follow-up period				*		*	Thoracic aorta size	9
Yes/No	Examination	The re-operation of patients during follow-up period		*				*	Re-operation	10
Yes/No	Echocardiography at baseline and follow-up echocardiography	The pathology of AV that is mentioned in echocardiographic report and the diagnosis of patient, including AV stenosis and AV insufficiency		*				*	AV pathology	11

12	Grading of AI	*				*		The grading of AV insufficiency defined as mild, moderate, or severe at preoperative echocardiography and follow-up period	Echocardiography	Yes/No
13	Grading of AS	*				*		The grading of AS defined as mild, moderate, or severe at preoperative echocardiography and follow-up period	Echocardiography	Yes/No
14	Death	*				*		Mortality of patients during follow-up period as in-hospital or late mortality	Database	Yes/No

جدول زمان بندی

ردیف	فعالیت	مسئول	ماه											
			1	2	3	4	5	6	7	8	9	10	11	12
1	Database review and data collection													
2	Data cleaning and data handling													
3	Report													

بیان مسئله

The bicuspid aortic valve (BAV) deserves proper attention as a prevalent valvular pathology with a tendency to develop obstruction and insufficiency. It is almost 3 times more common in males than females.[1] Not only does BAV lead to important valvular complications such as aortic stenosis, aortic regurgitation and infective endocarditis, but also BAV is associated with an underlying aortopathy.[2] The BAV is recognized as underlying almost 50% of isolated severe aortic stenosis cases requiring surgery,[3] and has been extensively associated with life-threatening outcomes such as aortic dissection and infective endocarditis.[4] BAV relates to several congenital and genetic disorders with cardiovascular manifestations, often associated with congenital left-sided obstructive lesions (i.e., coarctation of the aorta, Shone complex),[5] ventricular septal defect,[6] and syndromic conditions (i.e., Turner, Loeys-Dietz), and familial thoracic aortic aneurysm and dissection disease due to smooth muscle α-actin (ACTA2) gene mutations, as well.[7, 8] BAV has high heritability; however, there are no standard guidelines for providing genetic counseling to patients and families with BAV. Associations of BAV with other syndromes and connective tissue disorders, recognizing the necessity for evaluation by a clinical geneticist for diagnosis, accurate recurrence risk information, and relevant family screening recommendations.[9] So, it becomes necessary to accrue very large numbers of BAV patients with long-term follow-up, such as in a multicenter, international registry, to identify new factors associated with these complications.

The natural history of BAV is somewhat dependent on associated abnormalities. It can range from severe aortic stenosis in childhood to asymptomatic disease until old age. There have indeed been incidental findings of a minimally calcified BAV in patients in their 70s.[10] A cohort of 212 asymptomatic patients with BAV (age 32 ± 20 years) were found to have the same 20-year survival rate as the normal population (around 90%) but an increased frequency of cardiac events including aortic valve surgery, ascending aorta surgery and any other cardiovascular surgery. Predictive factors for cardiovascular events were found to be age ≥50 years and valve degeneration at diagnosis while baseline ascending aorta ≥40 mm independently predicted surgery for aorta dilatation.[11] The fetus can generally survive with severe aortic stenosis due to blood flow through the right side of the heart; however in infancy there is usually a sudden decline in cardiovascular status.[12] In adults with BAV, stenosis occurs by similar methods to the process in patients with tricuspid aortic valves. It is felt to be due to leaflet calcification.[13] The BAV is often associated with aortopathies, including dilatation of the aortic root and the ascending aorta. This can lead to aneurysm and dissection.[14]

The only treatments to offer any sort of curative option are surgical. Medical therapies are to try and alleviate symptoms and slow progression. The joint ACC/AHA guidelines suggested use of beta-blockers as first-line therapy in these patients.[15] In patients with aortopathy in Marfan syndrome there is also a suggestion that angiotensin converting enzyme inhibitors may have a role to play; however, the evidence in BAV is still lacking.[16] In addition to surgical modalities, transcatheter aortic valve implantation (TAVI) has also been demonstrated that can be implemented in high-risk or inoperable individuals with BAV.[17, 18] Indications for valve surgery in patients with BAV are similar to those with tricuspid aortic valves. In children it is usually not practical to do aortic valve replacement as they outgrow the prosthetic valve. Due to the lack of valve calcification in children balloon valvuloplasty is possible and is the management strategy of choice.[19] Regarding currently available therapies for BAV, contemporary observations also mandate clinical research to improve surgical repair of the non-calcified purely regurgitant BAV.[20] Moreover, patients with BAV have a low risk of aortic dissection as a population; however, patients with aneurysms of 45 mm or larger have a higher incidence of dissection (0.45% per year) and must be followed up carefully.[21] It has been demonstrated that patients undergoing operations for BAV disease should be considered for concomitant replacement of the ascending aorta if the diameter is 45 mm or greater.[22]

Hence, in this retrospective cohort study, we sought to evaluate the outcomes of patients with BAV who underwent surgical treatment or receive medical management in Rajaie CMRC between 1382 and 1398. Mid- to long-term follow-up of patients in our clinics accompanied by echocardiographic and imaging evaluations would provide us data for identifying the predictors of outcomes in such vulnerable patients.	
The bicuspid aortic valve (BAV) deserves proper attention as a prevalent valvular pathology with a tendency to develop obstruction and insufficiency. Not only does BAV lead to important valvular complications such as aortic stenosis, aortic regurgitation and infective endocarditis, but also BAV is associated with an underlying aortopathy. Associations of BAV with other syndromes and connective tissue disorders, recognizing the necessity for evaluation by a clinical geneticist for diagnosis, accurate recurrence risk information, and relevant family screening recommendations. The natural history of BAV is somewhat dependent on associated abnormalities. It can range from severe aortic stenosis in childhood to asymptomatic disease until old age. The only treatments to offer any sort of curative option are surgical. Medical therapies are to try and alleviate symptoms and slow progression. Indications for valve surgery in patients with BAV are similar to those with tricuspid aortic valves. In children it is usually not practical to do aortic valve replacement as they outgrow the prosthetic valve. Due to the lack of valve calcification in children balloon valvuloplasty is possible and is the management strategy of choice. It has been demonstrated that patients undergoing operations for BAV disease should be considered for concomitant replacement of the ascending aorta if the diameter is 45 mm or greater. Given these points, it becomes necessary to accrue very large numbers of BAV patients with long-term follow-up to identify new factors associated with complications and/or better outcomes.	ضرورت اجرا
The morphology of the BAV may predict the severity of valve dysfunction. Therefore, Fernandes et al[23] assessed the relationship between BAV, aortic coarctation, and the degree of valve pathology in children. A retrospective review of 1,135 patients with BAV who were identified between 1986 and 1999 was performed. Patients younger than 18 years of age with BAV that was identifiable via echocardiography were included. The most recent or last study of each patient before intervention or endocarditis was reviewed. Mild stenosis was defined as a valve gradient ≥2 m/s, moderate or greater aortic stenosis as ≥3.5 m/s. Aortic regurgitation was quantified using standard criteria. Median age was 3 years (range, 1 day to 17.9 years), and 67% of the patients were male. Right-coronary and left-coronary leaflet fusion were the most common types of BAV (70%). Aortic stenosis that was moderate or greater was observed most often in patients with right-coronary and non-coronary leaflet fusion (odds ratio 2.4, 95% CI 1.6 to 3.6; $p \leq 0.001$). Similarly, right-coronary and non-coronary leaflet fusion was more often associated with moderate aortic regurgitation or greater (odds ratio 2.4, 95% CI 1.2 to 4.7; $p = 0.01$). The majority of patients with aortic coarctation had fusion of the right-coronary and left-coronary leaflets (89%), and aortic coarctation was associated with lesser degrees of valve stenosis or regurgitation. Analysis of BAV morphology is of clinical and prognostic relevance. Fusion of the right-coronary and non-coronary leaflets was associated with more significant valve pathology, whereas fusion of the right-coronary and left-coronary leaflets was associated with aortic coarctation and less aortic valve pathology.	بررسی متون

BAV has been thought to cause frequent and severe aortic complications, and it has been evaluated in a cohort study with long-term follow-up. In a retrospective cohort study,[21] they conducted comprehensive assessment of aortic complications of patients with BAV living in a population-based setting. They analyzed long-term follow-up of a cohort diagnosed with definite BAV by echocardiography from 1980 to 1999 and searched for aortic complications of patients whose BAV had gone undiagnosed. The last year of follow-up was 2008-2009. The cohort included 416 consecutive patients with definite BAV diagnosed by echocardiography, mean follow-up of 16 years. Aortic dissection occurred in 2 of 416 patients; incidence of 3.1 (95% CI, 0.5-9.5) cases per 10,000 patient-years, age-adjusted relative-risk 8.4 (95% CI, 2.1-33.5; p = 0.003) compared with the county's general population. Aortic dissection incidences for patients 50 years or older at baseline and bearers of aortic aneurysms at baseline were 17.4 (95% CI, 2.9-53.6) and 44.9 (95% CI, 7.5-138.5) cases per 10,000 patient-years, respectively. Comprehensive search for aortic dissections in undiagnosed BAVs revealed 2 additional patients, allowing estimation of aortic dissection incidence in BAV patients irrespective of diagnosis status (1.5; 95% CI, 0.4-3.8 cases per 10,000 patient-years), which was similar to the diagnosed cohort. Of 384 patients without baseline aneurysms, 49 developed aneurysms at follow-up, incidence of 84.9 (95% CI, 63.3-110.9) cases per 10,000 patient-years and an age-adjusted relative risk 86.2 (95% CI, 65.1-114; p <0.001 compared with the general population). The 25-year rate of aortic surgery was 25% (95% CI, 17.2%-32.8%). They concluded that the incidence of aortic dissection in patients with BAV over a mean of 16 years of follow-up was low but significantly higher than in the general population.

The natural history of aortopathies is different among patients with or without BAV. Davies et al[24] reviewed clinical characteristics of 514 patients (326 male, 188 female) with unrepaired ascending aortic aneurysms followed from 1985 to 2005. Seventy patients (13.4%) diagnosed with BAV form group A; the remaining 445 patients form group B. Growth rates and risk factors for complications were assessed. Patients in group A had a lower incidence of hypertension (p = 0.018), carotid artery disease, and stroke (p = 0.018), and presented at an earlier age (49.0 versus 64.2 years, p <0.001). Group A also had a higher rate of aortic growth (0.19 versus 0.13 cm/year, p = 0.010). The incidence of rupture and dissection were similar. Overall survival was better among patients with BAV (p <0.001). Among patients with BAV, those with aortic stenosis had a higher risk of rupture, dissection, or death before operative repair than did those with normally functioning valves (odds ratio 10.475, 95% CI 1.15 to 95.15). Based on this study, despite the faster rates of growth, however, patients with BAV have similar rates of aortic rupture, dissection, and death and improved long-term survival. Contributing to this finding may be the lower incidence of comorbidities, the younger age at presentation, and the more attentive follow-up with earlier operative repair.

Michelena et al[25] evaluated the clinical outcome of patients diagnosed with normal or mildly dysfunctional BAV who were asymptomatic. In 212 asymptomatic community residents from Olmsted County, Minnesota, the BAV was diagnosed between 1980 and 1999 with ejection fraction ≥50% and aortic regurgitation or stenosis, absent or mild. Aortic valve degeneration at diagnosis was scored echocardiographically for calcification, thickening, and mobility reduction (0 to 3 each), with scores ranging from 0 to 9. At diagnosis, ejection fraction was 63±5% and left ventricular diameter was 48±9 mm. Survival 20 years after diagnosis was 90±3%, identical to the general population (p = 0.72). Twenty years after diagnosis, heart failure, new cardiac symptoms, and cardiovascular medical events occurred in 7±2%, 26±4%, and 33±5%, respectively. Twenty years after diagnosis, aortic valve surgery, ascending aortic surgery, or any cardiovascular surgery was required in 24±4%, 5±2%, and 27±4% at a younger age than the general population (p <0.001). No aortic dissection occurred. Thus, cardiovascular medical or surgical events occurred in 42±5% 20 years after diagnosis. Independent predictors of cardiovascular events were age ≥50 years (risk ratio, 3.0; 95% CI, 1.5 to 5.7; p <0.01) and valve degeneration at diagnosis (risk ratio, 2.4; 95% CI, 1.2 to 4.5; p = 0.016; >70% events at 20 years). Baseline ascending aorta ≥40 mm independently predicted surgery for aorta dilatation (risk ratio, 10.8; 95% CI, 1.8 to 77.3; p <0.01). In the community, asymptomatic patients with BAV and no or minimal hemodynamic abnormality enjoy excellent long-term survival but incur frequent cardiovascular events,

particularly with progressive valve dysfunction. Echocardiographic valve degeneration at diagnosis separates higher-risk patients who require regular assessment from lower-risk patients who require only episodic follow-up.

Tzemos et al[26] evaluated the frequency and predictors of cardiac outcomes in a large consecutive series of adults with BAV. The cohort study examined cardiac outcomes in 642 consecutive ambulatory adults (35 ± 16 years; 68% male) with BAV presenting to a Canadian congenital cardiac center from 1994 through 2001 and followed up for a mean period of 9 ± 5 years. Frequency and predictors of major cardiac events were determined by multivariate analysis. Mortality rate in the study group was compared with age- and sex-matched population estimates. Mortality and cause of death were determined. Primary cardiac events were defined as the occurrence of any of the following complications: cardiac death, intervention on the aortic valve or ascending aorta, aortic dissection or aneurysm, or congestive heart failure requiring hospital admission during the follow-up period. During the follow-up period, there were 28 deaths (4%). One or more primary cardiac events occurred in 161 patients (25%), which included cardiac death in 17 patients (3%), intervention on aortic valve or ascending aorta in 142 patients (22%), aortic dissection or aneurysm in 11 patients (2%), or congestive heart failure requiring hospital admission in 16 patients (2%). Independent predictors of primary cardiac events were age older than 30 years (hazard ratio [HR], 3.01; 95% confidence interval [CI], 2.15-4.19; p <0.001), moderate or severe aortic stenosis (HR, 5.67; 95% CI, 4.16-7.80; p< 0.001), and moderate or severe aortic regurgitation (HR, 2.68; 95% CI, 1.93-3.76; p <0.001). The 10-year survival rate of the study group (96%) was not significantly different from population estimates (97%; p = 0.71). At last follow-up, 280 patients (45%) had dilated aortic sinus and/or ascending aorta. Based on their findings, over the mean follow-up duration of 9 years, survival rates were not lower than for the general population.

Borger et al[22] conducted a study to find that the replacement of the ascending aorta should be performed at which diameter in patients with BAV. They reviewed all patients with BAVs undergoing aortic valve replacement from 1979 through 1993 (n = 201). Patients undergoing concomitant replacement of the ascending aorta were excluded. Follow-up was obtained on 98% of patients and was 10.3 ± 3.8 years. The average patient age was 56 ± 15 years, and 76% were male. The ascending aorta was normal (<4.0 cm) in 115 (57%) patients, mildly dilated (4.0-4.4 cm) in 64 (32%) patients, and moderately dilated (4.5-4.9 cm) in 22 (11%) patients. All patients with bicuspid aortic valves with marked dilation (>5.0 cm) underwent replacement of the ascending aorta and were therefore excluded. Fifteen-year survival was 67%. During follow-up, 44 patients required reoperation, predominantly for aortic valve prosthesis failure. Twenty-two patients had long-term complications related to the ascending aorta: 18 required an operative procedure to replace the ascending aorta (for aortic aneurysm), 1 had aortic dissection, and 3 experienced sudden cardiac death. Fifteen-year freedom from ascending aorta-related complications was 86%, 81%, and 43% in patients with an aortic diameter of less than 4.0 cm, 4.0 to 4.4 cm, and 4.5 to 4.9 cm, respectively (p < 0.001). Accordingly, they concluded that patients undergoing operations for BAV disease should be considered for concomitant replacement of the ascending aorta if the diameter is 4.5 cm or greater.

Reconstruction of the regurgitant BAV has been performed for more than two decades. Aicher et al[20] evaluated 316 patients (49 ± 14 years; 84.8% male) underwent reconstruction of a regurgitant BAV. Intraoperative assessment included extent of fusion, root dimensions, circumferential orientation of the 2 normal commissures (>160° vs. ≤160°), and effective height after repair. Cusp pathology was treated by central plication (n=277), triangular resection (n=138), or pericardial patch (n=94). Root dilatation was treated by subcommissural plication (n=100), root

remodeling (n=122), or valve reimplantation (n=2). All patients were followed up echocardiographically (mean, 4 ± 3.1 years). Clinical and morphological parameters were analyzed for correlation with 10-year freedom from reoperation with the Cox proportional hazards model. Hospital mortality was 0.63%; survival was 92% at 10 years. Freedom from reoperation at 5 and 10 years was 88% and 81%; freedom from valve replacement, 95% and 84%. By univariable analysis, statistically significant predictors of reoperation were age (HR = 0.97), aortoventricular diameter (HR = 1.24), effective height (HR = 0.76), commissural orientation (HR = 0.95), use of a pericardial patch (HR = 7.63), no root replacement (HR = 3.80), subcommissural plication (HR = 2.07), and preoperative aortic regurgitation grade 3 or greater. By multivariable analysis, statistically significant predictors for reoperation were age (HR=0.96), aortoventricular diameter (HR = 1.30), effective height (HR = 0.74), commissural orientation (HR = 0.96), and use of a pericardial patch (HR = 5.16). Based on these results, the reconstruction of BAV can be performed reproducibly with good early results. Recurrence and progression of regurgitation, however, may occur, depending primarily on anatomic features of the valve.

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اهداف: هدف اصلی، اهداف اختصاصی، هدف کاربردی

اهداف (خروجی ها) اصلی طرح[8]:

To evaluate mid- to long-term outcomes of patients with BAV undergoing medical and/or surgical management

اهداف (خروجی ها) اختصاصی طرح[9] :

۱. Determining the association between age and survival during follow-up period in patients with BAV undergoing medical and/or surgical management

۲. Determining the association between sex and survival during follow-up period in patients with BAV undergoing medical and/or surgical management

۳. Determining the association between body mass index and survival during follow-up period in patients with BAV undergoing medical and/or surgical management

۴. Determining the association between concomitant congenital heart disease and survival during follow-up period in patients with BAV undergoing medical and/or surgical management

۵. Determining the effect of treatment type (medical vs. surgery) on survival during follow-up period in patients with BAV undergoing surgical management

۶. Determining the effect of concomitant surgical procedures on survival during follow-up period in patients with BAV undergoing surgical management

۷. Determining the predictors of aortopathies (increase in aneurysm size and/or dissection) during follow-up period in patients with BAV undergoing medical and/or surgical management

۸. Determining the predictors of surgical re-operation during follow-up period in patients with BAV undergoing surgical management

۹. Determining the predictors of progression of aortic valve dysfunction (insufficiency and/or stenosis) during follow-up period in patients with BAV undergoing medical and/or surgical management

۱۰. Determining the outcomes of patients with BAV by the severity of AV regurgitation and/or stenosis at baseline in patients undergoing medical and/or surgical management

۱۱. Determining the outcomes of patients with BAV by the presence of aorta aneurysm at baseline in patients undergoing medical and/or surgical management

اهدف کاربردی طرح[10]:

۱. To identify the predictors of outcomes of patients with BAV in our population ۲. To identify patients with BAV who can benefit more from early surgical intervention	
۱. Can age at baseline predict survival during follow-up period in patients with BAV undergoing medical and/or surgical management? ۲. Can sex predict survival during follow-up period in patients with BAV undergoing medical and/or surgical management? ۳. Can body mass index at baseline predict survival during follow-up period in patients with BAV undergoing medical and/or surgical management? ۴. Can concomitant congenital heart disease at baseline predict survival during follow-up period in patients with BAV undergoing medical and/or surgical management? ۵. Does the treatment type (medical vs. surgery) influence on the survival during follow-up period in patients with BAV? ۶. Does concomitant surgical procedures influence on the survival during follow-up period in patients with BAV undergoing surgical management? ۷. Which factors can predict aortopathies (i.e., increase in aneurysm size and/or dissection) during follow-up period in patients with BAV undergoing medical and/or surgical management? ۸. Which factors can predict progression of aortic valve dysfunction (i.e., insufficiency and stenosis) during follow-up period in patients with BAV undergoing medical and/or surgical management? ۹. Which factors can predict surgical re-operation during follow-up period in patients with BAV undergoing surgical management? ۱۰. What is the association between the severity of AV regurgitation and/or stenosis at baseline and the outcomes of patients with BAV undergoing medical and/or surgical management? ۱۱. What is the association between the presence of aorta aneurysm at baseline and the outcomes of patients with BAV undergoing medical and/or surgical management?	فرضیات یا سوالات پژوهشی
In a retrospective manner, we will review the electronic database of Rajaie CMRC for finding data related to patients BAV undergoing medical and/or surgical management between 1382 and 1398. Data will comprise of baseline demographics, data on details of surgical repair or interventional modalities applied for the management of BAV, and echocardiographic examinations of patients during visit to echocardiographic laboratory and imaging department at first admission to the hospital and during follow-up period.	روش اجرا

Inclusion criteria include any individuals with BAV who visited Rajaie CMRC and underwent medical and/or surgical management with at least 6 months follow-up after first visit to our center.

Exclusion criteria include patients without complete data on management during visits to the clinics and echocardiographic examinations as well as the lack of data on echocardiographic examinations during follow-up period after surgical or interventional treatment.

During follow-up period we will collect data on re-operation, the changes in aneurysm size, the changes in AV dysfunction, and death.

Statistical analysis will be as follows:

According to the experience of the study investigators, the sample size will be at least 300 patients with BAV.

Comparing continuous variables between subgroups by an independent t-test or Mann-Whitney U test for two groups as well as ANOVA or Kruskal-Wallis test for more than two groups

Comparing categorical variables by chi-squared test

Logistic regression analysis for identifying predictors of outcomes

Kaplan-Meier curve for identifying survival and freedom from reoperation rate and aortopathies during follow-up period

Baseline characteristics' missing data will be managed using "Mean of nearby point". However, in the case of missing data for echocardiographic parameters, the case will be excluded from final analysis.

مشخصات ابزار جمع آوری اطلاعات و نحوه جمع آوری آن	All required data will be gathered via electronic database of Rajaie CMRC. All data will be entered into the Excel datasheets after extraction from hospital database, and then those will be transferred into statistical software.
روش محاسبه حجم نمونه و تعدادآن	All available data in the hospital database will be evaluated and patients with BAV who are under evaluations by Rajaie CMRC's physicians and have sufficient and reliable data will be entered in this study.
ملاحظات اخلاقی	Confidentiality and anonymity of information will be considered by researchers. Study will receive the ethics code of Rajaie Heart Center .
محدودیتهای اجرایی طرح وروش کاهش آنها	The major limitation of this study will be the lack of data on surgical report and imaging evaluations for measuring the size of thoracic aorta and the severity of BAV dysfunction at baseline and follow-up period in our database. In cases with insufficient data, those will be excluded from survival analysis.
معیارهای ورود (فقط مربوط به طرحهای کارآزمایی بالینی)	
معیارهای خروج (فقط مربوط به طرحهای کارآزمایی بالینی)	
چگونگی تصادفی سازی و Concealment (فقط مربوط به طرحهای کارآزمایی بالینی)	
تعریف گروه مداخله (فقط مربوط به طرحهای کارآزمایی بالینی)	
تعریف گروه شاهدیامقایسه (فقط مربوط به طرحهای کارآزمایی بالینی)	
چگونگی کورسازی (Blinding) (فقط مربوط به طرحهای کارآزمایی بالینی)	
پیامدها اولیه (primary) ثانویه (secondary) ایمنی (Safety) (فقط مربوط به طرحهای کارآزمایی بالینی)	
پیگیری (follow up) (فقط مربوط به طرحهای کارآزمایی بالینی)	

جدول متغیرها

نام متغیر	نقش متغیر	نوع متغیر	نوع متغیر کمی – پیوسته است؟	نوع متغیر کمی – گسسته است؟	نوع متغیر کیفی – رتبه ای است؟	نوع متغیر کیفی – اسمی است؟	واحد اندازه گیری	تعریف کاربردی	نحوه اندازه گیری
Age	مستقل	کمی	☑	☐	☐	☐	Year	The years of life	Examination
Sex	مستقل	کیفی	☐	☐	☐	☑	Male/Female	Phenotype	Examination
Weight	مستقل	کمی	☑	☐	☐	☐	Kg	Weight of body	Examination
Height	مستقل	کمی	☑	☐	☐	☐	Meter	Height of body	Examination
Body mass index	مستقل	کمی	☑	☐	☐	☐	Kg/m۲	Body mass index	Examination
Congenital heart disease	مستقل	کیفی	☐	☐	☐	☑	Yes/No	Defined based on guidelines appropriate for age groups and it is mentioned in hospital database in echocardiographic evaluations	Examination
AV pathology	مستقل	کیفی	☐	☐	☐	☑	Yes/No	The pathology of AV that is mentioned in echocardiographic report and the diagnosis of patient, including AV stenosis and AV insufficiency	Echocardiography at baseline and follow-up echocardiography
Grading of AI	مستقل	کیفی	☐	☐	☑	☐	Yes/No	The grading of AI defined as mild, moderate, or severe at preoperative echocardiography and follow-up period	Echocardiography
Grading of AS	مستقل	کیفی	☐	☐	☑	☐	Yes/No	The grading of AS defined as mild, moderate, or severe at preoperative echocardiography and follow-up period	Echocardiography
Thoracic aorta size	مستقل	کمی	☑	☐	☐	☐	mm	The size of thoracic aorta measured by echocardiography at baseline and follow-up period	Echocardiography
Type of BAV management	مستقل	کیفی	☐	☐	☐	☑	Yes/No	The surgical or interventional	Database

		modalities used for BAV repair as well as the medical management of BAV cases							
Death	مستقل	کیفی					Yes/No	Mortality of patients during follow-up period as in-hospital or late mortality	Database
Concomitant surgery	مستقل	کیفی					Yes/No	Any surgeries performed concomitant with AV repair	Database
Re-operation	مستقل	کیفی					Yes/No	The re-operation of patients during follow-up period	Examination

زمانبندی و مراحل اجرا

شرح مختصر مرحله	درصد مرحله	مدت اجرا – ماه	از تاریخ	تا تاریخ
Database review and data collection		۲	۱۳۹۹/۱۲/۲۰	۱۴۰۰/۰۲/۲۰
Data cleaning and data handling		۶	۱۴۰۰/۰۲/۲۰	۱۴۰۱/۰۷/۲۰
Report		۴	۱۴۰۰/۰۷/۲۰	۱۴۰۰/۱۱/۲۰

ملاحظات اخلاقی

شما اجازه مشاهده این فرم را ندارید

هزینه وسایل و مواد مورد نیاز

نوع	نام دستگاه/ وسیله/ مواد	تعداد مورد نیاز	قیمت دستگاه/ وسیله/ مواد – ریال	کشور سازنده	شرکت سازنده	شرکت فروشنده	محل تامین اعتبار	جمع کل هزینه به ریال

هزینه پرسنلی

نام و نام خانوادگی	توصیف دقیق فعالیتی که فرد در این تحقیق باید انجام دهد	کل حق‌الزحمه – ریال
پرهام هاشمی(۱۹۴۹)	جمع آوری دیتا	۳۰,۰۰۰,۰۰۰
مینا دانشمندی(۱۸۸۹)	وارد کردن دیتا	۳۰,۰۰۰,۰۰۰
یوسف مقدم(۴۳۱)	همکاری از بخش کامپیوتر	۲۰,۰۰۰,۰۰۰
یوسف رضایی(۱۰۵۶)	نوشتن مقاله	۲۰,۰۰۰,۰۰۰

هومن بخشنده آبکنار(۱۰۳)	آنالیز	۱۰,۰۰۰,۰۰۰

جمع کل – ریال : ۱۱۰,۰۰۰,۰۰۰

هزینه آزمایشات و خدمات تخصصی

نام خدمت	نام مؤسسه ارائه کننده	تعداد یا مقدار لازم	قیمت واحد – ریال	قیمت کل – ریال
رکوردی یافت نشد				

هزینه مسافرت

مقصد	تعداد مسافرت در مدت اجرای طرح و منظور آن	نوع وسیله نقلیه	تعداد مسافرت	مبلغ
رکوردی یافت نشد				

هزینه کتب، نشریات و مقالات

نوع هزینه	توضیحات	مبلغ – ریال
رکوردی یافت نشد		

سایر هزینه ها

نوع هزینه	مبلغ – ریال
رکوردی یافت نشد	

کل اعتبار درخواست شده

هزینه پرسنلی (هیات علمی و غیر هیات علمی)	هزینه مواد مصرفی	هزینه مواد غیر مصرفی	هزینه تجهیزات،موادوخدمات موجوددر مرکز	هزینه مسافرت	هزینه چاپ و تکثیر	سایر هزینه ها	جمع کل هزینه – ریال
۱۱۰,۰۰۰,۰۰۰							۱۱۰,۰۰۰,۰۰۰