بیمارستان قلب شهید رجایی

بررسی نتایج درمان دارویی یا جراحی در بیماران نارسایی غیر ایسکمیک میترال مراجعه کننده به بیمارستان قلب و عروق شهید رجایی در طی سال های ۹۸-۸۲

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عنوان لاتین طرح:	The evaluation of outcomes of functional mitral regurgitation in patients undergoing medical or surgical therapies visited Rajaie CMRC between ۱۳۸۲ and ۱۳۹۸
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رده	نوع ارتباط با مرکز
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متون پیشنهاد

آیتم اطلاعات تفضیلی	متن
جدول متغیرها	
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بیان مسئله	Functional mitral regurgitation (MR) is defined as cases caused by cardiomyopathies (i.e., dilated and hypertrophic cardiomyopathies) or right ventricular pacing creating left ventricular (LV) asynchrony.[1-3] Secondary MR results from a combination of processes,[4, 5] including 1) Tethering or tenting of mitral leaflets caused by papillary muscle displacement, regional and/or global LV remodeling, and mitral annular dilation 2) Impaired closing as a result of impaired LV contractility, LV dyssynchrony, papillary muscle dyssynchrony, and/or reduced mitral annular contraction 3) Annular enlargement secondary to LV dilatation and/or LV remodeling with papillary muscle displacement. Echocardiographic studies of functional MR have shown that regurgitant flow varies throughout systole, so there is an early systolic peak, a midsystolic decrease, and a smaller late systolic peak. These variations occur in association with changes in regurgitant orifice area and are more closely associated with changes in transmitral pressure gradient than with mitral annular area.[6] MR burdens the LV with a volume load that leads to a series of compensatory myocardial and circulatory adjustments. These

adjustments vary over the prolonged course of the disorder, so that the changes that are operative in acute or subacute MR are eventually replaced by other compensatory mechanisms.[7] Comprehensive evaluation of the patient with HF and secondary MR requires a detailed medical history and physical examination, with laboratory, electrocardiographic, and echocardiographic assessment. Secondary MR can be categorized into 4 stages that define prognosis and guide therapy: 1) at risk of secondary MR; 2) progressive secondary MR; 3) asymptomatic severe secondary MR; and 4) symptomatic severe secondary MR.[8] The cornerstone of diagnostic evaluation of MR is echocardiography, with transesophageal and transthoracic echocardiography playing complementary roles. Since patients may or may not experience symptoms during the transition from compensated to decompensated chronic MR, monitoring for evidence of decompensation, including periodic measurement of LV size and systolic function by echocardiography, is required.[9]

Functional MR due to LV dysfunction is associated with a poor prognosis.[2] The management of patients with chronic secondary MR requires an understanding of the pathophysiology and natural history of the disease and the efficacy and timing of treatment, particularly mitral valve repair and replacement.[10] There is a strong association between the severity of secondary MR and both all-cause mortality and heart failure (HF) hospitalizations.[2, 11] On the other hand, whether this relationship is causal and whether reducing MR improves the prognosis of patient remain unknown. Moreover, current therapies targeting pathological ventricular remodeling, such as the use of inhibitors of the renin-angiotensin-aldosterone axis and beta-blocking agents, have manifested significant effectiveness in reducing morbidity and mortality in patients with systolic HF,[12] and there is some evidence from small-sized studies that those agents can reduce the severity of FMR in the short term.[13]

Hence, in this study we sought to evaluate the outcomes and predictors of prognosis among patients with functional MR visited our clinics in Rajaie CMRC who underwent medical and/or surgical treatments between 1382 and 1398.

ضرورت اجرا

In this study, functional mitral regurgitation (MR) is defined as cases caused by cardiomyopathies (i.e., dilated and hypertrophic cardiomyopathies) or right ventricular pacing creating left ventricular (LV) asynchrony. Echocardiographic studies of functional MR have shown that regurgitant flow varies throughout systole. These variations occur in association with changes in regurgitant orifice area and are more closely associated with changes in transmitral pressure gradient than with mitral annular area. MR burdens the LV with a volume load that leads to a series of compensatory myocardial and circulatory adjustments. Comprehensive evaluation of the patient with HF and secondary MR requires a detailed medical history and physical examination, with laboratory, electrocardiographic, and echocardiographic assessment. The cornerstone of diagnostic evaluation of MR is echocardiography, with transesophageal and transthoracic echocardiography playing complementary roles. Monitoring is required for evidence of decompensation, including periodic measurement of LV size and systolic function by echocardiography. There is a strong association between the severity of secondary MR and both all-cause mortality and heart failure (HF) hospitalizations. On the other hand, whether this relationship is causal and whether reducing MR improves the prognosis of patient remain unknown. Hence, in this study we sought to evaluate the outcomes and predictors of prognosis among patients with functional MR visited our clinics in Rajaie CMRC who underwent medical and/or surgical therapies.

بررسی متون

Functional MR is a common finding in patients with HF, but its effect on outcome is less investigated. Rossi et al[2] evaluated the prognostic value of functional MR in patients with HF. So, a total of 1256 patients with HF due to ischemic and non-ischemic dilated cardiomyopathy were retrospectively recruited. The clinical end point was a composite of all-cause mortality and hospitalization for worsening HF. FMR was quantitatively determined by measuring vena contracta (VC) or effective regurgitant orifice (ERO) or regurgitant volume (RV). Severe functional MR was defined as ERO >0.2 cm2 or RV >30 ml or VC >0.4 cm. Restrictive mitral filling pattern (RMP) was defined as E-wave deceleration time <140 ms. The study population comprised 1256 patients (mean age 67±11; 78% male) with HF due to dilated cardiomyopathy: 27% had no functional MR, 49% mild to moderate functional MR and 24% severe functional MR. There was a powerful association between severe functional MR and prognosis (hazard ratio[HR]=2.0, 95% confidence interval [CI] 1.5 to 2.6; p<0.0001) after adjustment of left ventricular ejection fraction and RMP. The independent association of severe functional MR with prognosis was confirmed in patients with ischemic dilated cardiomyopathy (HR=2.0, 95% CI 1.4 to 2.7; p<0.0001) and non-ischemic dilated cardiomyopathy (HR=1.9, 95% CI 1.3 to 2.9; p=0.002). They concluded that a quantitatively defined functional MR was strongly associated with the outcome of patients with HF, independently of LV function.

Bursi et al[11] examined the independent prognostic role of functional MR and its impact across the severity of chronic HF in a large population of outpatients with systolic chronic HF followed at two multidisciplinary clinics. Echocardiography was performed upon enrolment in 469 chronic HF patients. Follow-up for death and heart transplant was updated on January 2007. Five-year transplant-free survival was 82.7% in patients with no or Grade I functional MR, 64.4% in Grade II, 58.5% in Grade III, and 46.5% in Grade IV (p <0.001). There was a strong graded association between functional MR and the long-term risk of death and heart transplant, which remained significant after multivariable adjustment (p = 0.003). The association between functional MR and events was strong and independent in patients with less severe symptoms and in those at lower overall risk based on a propensity score analysis, while it was not significant in patients with more advanced chronic HF or in the high-risk subgroup (p <0.001 for interactions). Accordingly, it can be concluded that functional MR is an independent determinant of death and heart transplantation only in less severe chronic HF and in patients with a lower risk profile. This finding indicates that functional MR plays a major role in the early phase of chronic HF, suggesting that this should be the focus of strategies attempting to reduce it.

Kajimoto et al[14] also evaluated the association of functional MR, preserved or reduced ejection fraction (EF), and ischemic or non-ischemic origin with outcomes in patients discharged alive after hospitalization for acute decompensated HF. Of the 4,842 patients enrolled in the Acute Decompensated Heart Failure Syndromes (ATTEND) registry, 3357 patients were evaluated to assess the association of functional MR, preserved or reduced EF, and ischemic or non-ischemic origin with the primary end point (all-cause death and readmission for HF after discharge). At the time of discharge, functional MR was assessed semiquantitatively (classified as none, mild, or moderate to severe) by color Doppler analysis of the regurgitant jet area. According to multivariable analysis, in the ischemic group, either mild or moderate to severe functional MR in patients with a preserved EF had a significantly higher risk of the primary end point than patients without functional MR (HR 1.60; 95% CI 1.12 to 2.29; p = 0.010 and HR 1.98; 95% CI 1.30 to 3.01; p = 0.001, respectively). In patients with

reduced EF with an ischemic origin, only moderate to severe functional MR was associated with a significantly higher risk of the primary end point (HR 1.67; 95% CI 1.11 to 2.50; p = 0.014). In the non-ischemic group, there was no significant association between functional MR and the primary end point in patients with either a preserved or reduced EF. In conclusion, among patients with acute decompensated HF with a preserved or reduced EF, the association of functional MR with adverse outcomes may differ between patients who had an ischemic or non-ischemic origin of HF.

The effect of medical management of functional MR on its prognosis and improving the severity of MR is not well-recognized. In a prospective study, Nasser et al[15] assessed the extent of functional MR at baseline and after a median follow-up period of 50 months in 163 consecutive patients with LV ejection fraction <40%. Severe functional MR was defined as MR grade 3-4. All of the patients received the maximal tolerable doses of their HF medications. Major adverse cardiac events were defined as a composite of all-cause death and the need for heart transplantation or hospitalization for HF and/or malignant arrhythmias. During the follow-up period, 38% of the severe MR patients showed an improvement to non-severe MR (MR grade <3), whereas 18% of the non-severe MR patients developed severe MR despite optimal HF treatment. Cox regression analysis revealed that the presence of sustained severe MR or worsening of MR was the most important independent prognostic determinant with an adjusted odds ratio of 2.5 (95% CI 1.5 to 4.3, major adverse cardiac events 83% vs. 43%). In addition, those patients showed a 13% increase in LV end-diastolic volume index, whereas the patients with improvement in their severe MR showed a 2% decrease (p = 0.01). They found that severe functional MR was successfully treated with medication in almost 40% and was associated with prevention of left ventricular adverse remodeling and with an improved long-term prognosis.

It remains unclear whether surgical or transcatheter mitral valve repair for secondary mitral MR in patients with non-ischemic cardiomyopathy reverse the underlying LV pathophysiology. Kamperidis and colleagues[16] hypothesized that mitral valve repair improves LV systolic function and forward flow and induces LV reverse remodeling in this group of patients. Seventy-six patients (65 ± 14 years old, 43% male) with non-ischemic cardiomyopathy and moderate to severe chronic secondary MR treated successfully with transcatheter or surgical mitral valve repair were evaluated. Transthoracic echocardiography was performed at baseline, discharge and 6 months post-repair. After mitral valve repair, EF, and LV global longitudinal strain (GLS) corrected for LV end-diastolic volume remained unchanged over time (p = 0.90 and p = 0.96, respectively). In contrast, LV forward flow increased significantly over time (stroke volume index: from 20 ± 7 to 29 ± 8 and 26 ± 8 mL/m^2, p <0.001; cardiac index: from 1.50 ± 0.44 to 2.36 ± 0.60 and 2.01 ± 0.48 L/min/m^2, p <0.001). In addition, LV end-diastolic and end-systolic volume index significantly reduced over time (from 87 ± 42 to 70 ± 33 and 75 ± 39 mL/m^2, p <0.001; and from 60 ± 35 to 50 ± 30 and 53 ± 36 mL/m^2, p = 0.004, respectively). These changes were independent of the type of repair. Based on these findings, surgical and transcatheter mitral valve repair for secondary MR in patients with non-ischemic dilated cardiomyopathy improved LV forward flow and induced LV reverse remodeling but did not change LV systolic function.

The impact of the severity of secondary MR on the risk of death and HF hospitalizations in patients with reduced LV systolic function is evaluated in a study by Mowakeea and colleagues.[17] They studied 615 consecutive patients with EF ≤35% by transthoracic echocardiography at a single medical center. Patients were divided into three groups of no MR, mild, or moderate to severe MR. The median follow-up was 2.9 years. The primary endpoint was a composite of death or HF hospitalizations. Compared with patients with no MR, the risk of death or HF hospitalizations was higher for mild MR (HR 1.7, p = 0.003) and moderate to severe MR (HR 2.7, p <0.001). The risk was also higher for the component endpoints of HF hospitalizations (mild MR: HR 2.3, p = 0.001; moderate to severe MR: HR 3.5, p <0.001) and death (mild MR: HR 1.6, p = 0.033; moderate to severe MR: HR 2.6, p <0.001). After adjustment for other covariates, MR was no longer significantly associated with death or HF hospitalizations, or death alone, but remained significantly associated with HF hospitalizations (mild MR: HR 1.7, p = 0.028; moderate to severe MR: HR 2.2, p = 0.002). Accordingly, in patients with reduced LV systolic function, secondary MR is associated with an increased risk of HF hospitalizations .but not death

Sannino et al[18] performed a meta-analysis to clarify the role of secondary MR in the outcomes of patients with ischemic or idiopathic cardiomyopathies. In 26 of 36 studies reporting LV function by secondary MR grade, increasing secondary MR severity was associated with worse LV function. When secondary MR was categorized as present or absent, all-cause mortality was significantly higher in the patients with secondary MR (17 studies, 26359 patients; risk ratio [RR],1.79; 95% CI, 1.47-2.18; p <0.001, I2 = 85%); when secondary MR was qualitatively graded, the incidence of all-cause mortality was significantly increased in patients having any degree of secondary MR compared with patients not having secondary MR (21 studies, 21081 patients; RR, 1.96; 95% CI, 1.67-2.31; p <0.001, I2 = 74%). Finally, when secondary MR was quantitatively graded, it remained associated with an increased all-cause mortality rate (9 studies, 3649 patients; RR, 1.97; 95% CI, 1.71-2.27; p <0.001, I2 = 0%). Moreover, secondary MR was associated with an increased risk of hospitalization for HF (16 studies, 10171 patients; RR, 2.26; 95% CI, 1.92-2.67; p <0.001, I2 = 41%), cardiac mortality (12 studies, 11896 patients; RR, 2.62; 95% CI, 1.87-3.69; p <0.001, I2 = 74%), and death, HF, and transplant (11 studies, 8256 patients; RR 1.63; 95% CI, 1.33-1.99; p <0.001, I2 = 78%). Accordingly, they concluded that secondary MR, even when mild, correlates with adverse outcomes in patients with ischemic or idiopathic cardiomyopathies. Because secondary MR is an intrinsic consequence of LV dysfunction, .causality between secondary MR and mortality should not be implied

Mitral valve annuloplasty (MVA) improves hemodynamics and symptoms in patients with MR, but effects on long-term mortality are not well established. Wu et al[19] retrospectively analyzed consecutive patients with significant MR and LV systolic dysfunction on echocardiography between 1995 and 2002. Cox regression analysis, including MVA as a time-dependent covariate and propensity scoring to adjust for differing probabilities of undergoing MVA, was used to identify predictors of death, LV assist device implantation, or United Network for Organ Sharing-1 heart transplantation. Of 682 patients identified, 419 were deemed surgical candidates; 126 underwent MVA. Propensity score derivation identified age, ejection fraction, and LV dimension to be associated with undergoing MVA. End points were reached in 120 (41%) of non-MVA and 62 (49%) of MVA patients. Increased risk of end point was associated with coronary artery disease (HR 1.80, 95% CI 1.30 to 2.49), blood urea nitrogen (HR 1.01, 95% CI 1.005 to 1.02), cancer (HR 2.77, 95% CI 1.45 to 5.30), and digoxin (HR 1.66, 95% CI 1.15 to 2.39). Reduced risk was associated with angiotensin-converting enzyme inhibitors (HR 0.65, 95% CI 0.44 to 0.95), beta-blockers (HR 0.59, 95% CI 0.42 to 0.83), mean arterial pressure (HR 0.98, 95% CI 0.97 to 0.99), and serum sodium (HR 0.93, 95% CI 0.90 to 0.96). MVA did not predict clinical outcome. In this analysis, there is no clearly demonstrable mortality benefit conferred by MVA for

significant MR with severe LV dysfunction. A prospective randomized control trial is warranted for further study of mortality with MVA in this population.

Non-sustained ventricular tachycardia (VT), frequent in un-operated severe MR, confers mortality risk (sudden death [SD] and cardiac death [CD]). The prognostic value of VT after mitral valve surgery (MVS) is little known. Olafiranye and colleagues[20] aimed to define this prognostic value and to assess its modulation by LV and/or right ventricular EF for mortality after MVS. In 57 patients (53% females, aged 58 ± 12 years) with severe MR prospectively followed before and after MVS, they performed 24-hour ambulatory electrocardiograms approximately annually. Ventricular EF values were determined within 1 year after MVS by radionuclide cineangiography. During 9.52 ± 3.49 endpoint-free follow-up years, late postoperative CD occurred in 11 patients (7 SD, 4 heart failures). In univariable analysis, >1 VT episode after MVS predicted SD ($p < 0.01$) and CD (SD or heart failure; $p < 0.04$). Subnormal postoperative right ventricular EF predicted CD ($p < 0.04$). When adjusted for preoperative age, gender, etiology or anti-arrhythmics, both postoperative VT and right ventricular EF predicted CD ($p \leq 0.05$). When postoperative VT and right ventricular EF were both in the multivariable model, only subnormal right ventricular EF predicted CD ($p < 0.04$). Among those with normal right ventricular EF, VT >1 episode predicted SD ($p = 0.03$). Based on these findings, postoperative VT and subnormal right ventricular EF can predict late postoperative deaths in non-ischemic MR. Consequently; such an assessment may aid patient management.

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اهداف: هدف اصلی، اهداف اختصاصی، هدف کاربردی

اهداف (خروجی ها) اصلی طرح[8]:

To evaluate the outcomes of functional MR in patients undergoing medical and/or surgical therapy

اهداف (خروجی ها) اختصاصی طرح[9] :

۱. Determining the predictors of outcomes of functional MR in patients undergoing medical therapy ((i.e., drugs prescribing for cardiomyopathy/HF

۲. Determining the association between age at baseline and outcomes of functional MR in patients (undergoing medical therapy (i.e., drugs prescribing for cardiomyopathy/HF

۳. Determining the association between sex and outcomes of functional MR in patients undergoing (medical therapy (i.e., drugs prescribing for cardiomyopathy/HF

۴. Determining the association between body mass index and outcomes of functional MR in patients (undergoing medical therapy (i.e., drugs prescribing for cardiomyopathy/HF

۵. Determining the predictors of outcomes of functional MR in patients undergoing surgical therapy

۶. Determining the association between sex and outcomes of functional MR in patients undergoing surgical therapy

۷. Determining the association between age and outcomes of functional MR in patients undergoing surgical therapy

۸. Determining the association between body mass index and outcomes of functional MR in patients undergoing surgical therapy

۹. Determining the predictors of outcomes of functional MR by the surgery type (repair vs. replacement) in patients undergoing surgical therapy

۱۰. Determining the outcomes of functional MR by the severity of MR at baseline in patients undergoing medical and/or surgical therapies

۱۱. Determining the outcomes of functional MR by the amount of mitral valve gradient at baseline in patients undergoing medical and/or surgical therapies

۱۲. Determining the outcomes of functional MR by the severity of LV systolic dysfunction (preserved vs. reduced) at baseline in patients undergoing medical and/or surgical therapies

۱۳. Determining the outcomes of functional MR by the changes of LV diameter (end-systolic and end-diastolic) at baseline in patients undergoing medical and/or surgical therapies

۱۴. Determining the outcomes of functional MR by the changes of left atrial size at baseline in patients undergoing medical and/or surgical therapies

اهدف کاربردی طرح[10]:

۱. To identify the predictors of outcomes of functional MR in our population after medical and/or surgical therapies

۲. To provide an evidence for identifying the main approach for the management of functional MR

فرضیات یا سوالات پژوهشی

۱. Demographic features and pathological findings can predict outcomes of functional MR in patients undergoing medical therapy.

۲. Age at baseline predicts survival during follow-up period in patients with functional MR undergoing medical therapy.

۳. Sex predicts survival during follow-up period in patients with functional MR undergoing medical therapy.

۴. Body mass index predicts survival during follow-up period in patients with functional MR undergoing medical therapy

۵. Demographic features can predict outcomes of functional MR in patients undergoing surgical therapy

۶. Age at baseline predicts survival during follow-up period in patients with functional MR undergoing surgical therapy?

۷. Sex predicts survival during follow-up period in patients with functional MR undergoing surgical therapy

۸. Body mass index predicts survival during follow-up period in patients with functional MR undergoing surgical therapy

۹. Surgery type (repair vs. replacement) impacts on the outcomes of functional MR in patients undergoing surgical therapy.

۱۰. There is an association between the severity of MR at baseline and the outcomes of functional MR in patients undergoing medical and/or surgical therapies.

۱۱. There is an association between the amount of mitral valve gradient at baseline and the outcomes of functional MR in patients undergoing medical and/or surgical therapies.

۱۲. There is an association between the severity of LV systolic dysfunction (preserved vs. reduced) at baseline and the outcomes of functional MR in patients undergoing medical and/or surgical therapies.

۱۳. There is an association between the changes of LV diameter (end-systolic and end-diastolic) at baseline and the outcomes of functional MR in patients undergoing medical and/or surgical therapies. ۱۴. There is an association between the changes of left atrial size at baseline and the outcomes of functional MR in patients undergoing medical and/or surgical therapies.	
In a retrospective manner, we will review the electronic database of Rajaie CMRC for finding data related to patients with non-ischemic functional MR between 1382 and 1398. Data will comprise of baseline demographics, data on surgical management of patients, and echocardiographic examinations of patients during visit to echocardiographic laboratory. Inclusion criteria include individuals greater than 18 years old with a diagnosis of functional MR based on echocardiographic examinations in Rajaie CMRC. According to coronary angiography or CT coronary angiography,patients who had normal epicardial coronary arteries or nonsignificant/mild lesions that could not explain severity of MR,consider non-ischemic FMR. The duration of follow-up will be at least 6 months after first visit. Exclusion criteria include MR secondary to ischemia, primary MR, and secondary MR to rheumatic heart disease. Patients without complete data on surgical modalities and echocardiographic examinations will also be excluded. In addition, the lack of data on echocardiographic examinations during follow-up after first visit will be considered as an exclusion criterion. Statistical analysis will be as follows: 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	روش اجرا

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 a diagnosis of non-ischemic functional MR associated with sufficient and reliable data will be entered in this study. The sample size of patients in our center is estimated to be about 300 patients.
ملاحظات اخلاقی	Confidentiality and anonymity of information will be considered by researchers. Study will receive the ethics code of Rajaie Cardiovascular, Medical and Research Center
محدودیتهای اجرایی طرح وروش کاهش آنها	The major limitation of this study will be the lack of data on surgical report and echocardiographic evaluations in our database. In cases with insufficient data, those will be excluded from final 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	Database
Sex	مستقل	کیفی	☐	☐	☐	☑	Male/Female	Phenotype	Database

Weight	مستقل	کمی	☑	☐	☐	☐	☐	Kg	Weight of body	Database
Height	مستقل	کمی	☑	☐	☐	☐	☐	Meter	Height of body	Database
Body mass index	مستقل	کمی	☑	☐	☐	☐	☐	Kg/m۲	Body mass index	Database
Hypertension	مستقل	کیفی	☐	☐	☐	☐	☑	Yes/No	Defined based on guidelines appropriate for age groups and it is mentioned in hospital database as the presence of hypertension history	Database
Non-ischemic functional MR	مستقل	کیفی	☐	☐	☑	☐	☐	mild, moderate, and severe grading	The secondary MR caused by etiologies rather than ischemic heart disease that is mentioned in echocardiographic report and diagnosis of .patient	Echocardiography at baseline and follow-up echocardiography
Left atrial size	وابسته	کمی	☑	☐	☐	☐	☐	cm	The size of left atrium measured by echocardiography	Database
Left atrial area	وابسته	کمی	☑	☐	☐	☐	☐	cm	The area of left atrium measured by echocardiography	Database
LV diameter	وابسته	کمی	☑	☐	☐	☐	☐	cm	The diameter of LV measured by echocardiography at end-systolic or end-diastolic	Database
LV ejection fraction	وابسته	کمی	☑	☐	☐	☐	☐	Percentage	The eyeball measurement of LV ejection fraction using echocardiography	Database
MV gradient	وابسته	کمی	☑	☐	☐	☐	☐	mm Hg	The amount of mean and peak gradients through mitral valve measured by echocardiography	Database
Treatment type	مستقل	کیفی	☐	☐	☐	☐	☑	Based on the type of drug class	The treatment modalities used for the management of MR, including surgery (repair vs. replacement) and medical (drugs used for HF and/or (cardiomyopathy	Database
Re-operation	وابسته	کیفی	☐	☐	☐	☐	☑	Yes/No	The re-operation of patients during follow-up period	Examination

Death	وابسته	کیفی	☐	☐	☐	☑	Yes/No	Mortality of patients during follow-up period as in-hospital or late mortality	Database
Concomitant surgery	وابسته	کیفی	☐	☐	☐	☑	Yes/No	Any surgeries performed concomitant with MV surgeries	Database
Re-hospitalization	وابسته	کیفی	☐	☐	☐	☑	Yes/No	Re-hospitalization during follow-up	Database
Cardiac Resynchronization Therapy	مستقل	کیفی	☐	☐	☐	☑	Yes/No	The use of cardiac resynchronization therapy in HF patients with functional MR to improve outcomes	Database

زمانبندی و مراحل اجرا

شرح مختصر مرحله	درصد مرحله	مدت اجرا – ماه	از تاریخ	تا تاریخ
Database review and data collection		۲		
Data cleaning and data handling		۶		
Report		۴		

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
بهاره کاظم برجی(۸۵۱)	جمع آوری دیتا	۳۰,۰۰۰,۰۰۰
فاطمه داودآبادی(۱۹۳۹)	وارد کردن دیتا	۳۰,۰۰۰,۰۰۰
پیمان طباطبایی(۸۵۰)	همکاری از بخش کامپیوتر	۲۰,۰۰۰,۰۰۰
هومن بخشنده آبکنار(۱۰۳)	آنالیز	۱۰,۰۰۰,۰۰۰

یوسف رضایی(۱۰۵۶)	نوشتن مقاله	۲۰,۰۰۰,۰۰۰

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