بیمارستان قلب شهید رجایی

بررسی نتایج جراحی دریچه میترال در کودکانی که طی سال های ۱۴۰۰-۱۳۸۲در بیمارستان قلب و عروق شهید رجایی تحت درمان قرار گرفته اند

شناسنامه طرح

کد رهگیری طرح:	۹۹۰۳۱
تاریخ تصویب پیش پروپوزال:	
عنوان طرح:	بررسی نتایج جراحی دریچه میترال در کودکانی که طی سال های ۱۴۰۰-۱۳۸۲در بیمارستان قلب و عروق شهید رجایی تحت درمان قرار گرفته اند
عنوان لاتین طرح:	The evaluation of mitral valve surgery outcomes in children undergoing treatment in Rajaie CMRC between ۱۳۸۲ and ۱۴۰۰
تلفن:	۲۳۹۲۲۱۹۹
پست الکترونیکی:	avtabib@yahoo.com
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تاریخ شروع:	۱۴۰۱/۰۳/۰۱
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محل اجرای	

طرح:	
محل اجرای طرح:	بیمارستان قلب شهید رجایی
سازمان مجری:	بیمارستان قلب شهید رجایی
سازمان مجری:	
دانشکده/محل خدمت:	Rajaie Cardiovascular Medical and Research Center, Iran University of Medical Sciences
رشته تخصصی:	قلب و عروق- اطفال
توضیحات:	
نوع طرح ها:	کاربردی

مجری / همکاران

نام و نام‌خانوادگی	سمت در طرح	نوع همکاری	توضیحات
آویسا طبیب	مجری اصلی / نویسنده مقاله	نظارت بر اجرای طرح	
نیلوفر سمیعی	همکار طرح	ارزیابی بالینی بیماران	
سعید حسینی	همکار طرح	ارزیابی بالینی بیماران	
علیرضا علیزاده قویدل	همکار طرح	ارزیابی بالینی بیماران	
غلامرضا عمرانی	همکار طرح	ارزیابی بالینی بیماران	
احمد محبی	همکار طرح	ارزیابی بالینی بیماران	
محمدمهدی پیغمبری	همکار طرح	ارزیابی بالینی بیماران	
گلنار مرتاض هجری	همکار طرح	جمع آوری نمونه ها	
یوسف رضایی	همکار طرح	نوشتن مقاله	
شایان نقشبندی	همکار طرح	مشاوره و آنالیز آماری	

فروزان قربانی	همکار طرح	سایر	

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	
جدول زمان بندی	
بیان مسئله	Mitral valve (MV) disease in children is quite variable and ranges from a cleft in the anterior leaflet to complex MV stenosis associated with Shone's complex or hypoplastic left heart syndrome. Mitral regurgitation in children may be associated with chronic rheumatic heart disease, and a number of congenital cardiac lesions may produce a similar lesion. The concomitant cardiac lesions complicating MV disease can dramatically affect clinical outcomes (۱). Surgical management of MV disease in infants and children has been a major therapeutic challenge for many years. It poses special surgical difficulties because of numerous morphological abnormalities requiring modifications (۲, ۳). In patients with congenital MV disease, reconstructive surgery is the primary goal and valve repair techniques are very effective (۴). However, in cases with severely dysplastic valves or after failed repair, mitral valve replacement (MVR) is the only option. The ideal prosthesis for MVR in children has not yet been found, and some physicians consider valve replacement in pediatric patients as a palliative procedure, as all available prostheses have significant drawbacks (۵). The incentive to avoid valve replacement in young children is fostered by the concern that operative mortality is high, ranging from ۱۰٪ to ۳۶٪. Other concerns include the potential

morbidity associated with long-term anticoagulation and the need for subsequent prosthetic valve replacements as the child grows (۶, ۷). Because valve repair is typically the initial objective of surgical therapy, most patients present for valve replacement after a failed attempt at valve repair. In this situation, therapeutic alternatives include further attempts at mitral valve repair, abandonment of the left ventricle with atrial septectomy and a Damus–Kaye–Stancel–type anastomosis, or transplantation. Important considerations in choosing among these therapeutic alternatives and MVR include estimates of early and late mortality, the likelihood of repeat valve replacement, and the incidence of late complications associated with prosthetic valve replacement in this age group (۱).

Therefore, in this cross-sectional study we sought to determine short-term to long-term outcomes of MV surgery in children undergoing surgery in our center from ۱۳۸۲-۱۴۰۰ year.

ضرورت اجرا

Mitral valve (MV) disease in children ranges from a cleft in the anterior leaflet to complex MV stenosis associated with Shone's complex or hypoplastic left heart syndrome. The concomitant cardiac lesions complicating MV disease can dramatically affect clinical outcomes. Surgical management of MV disease in infants and children has been a major therapeutic challenge for many years. In patients with congenital MV disease, reconstructive surgery is the primary goal and valve repair techniques are very effective. However, in cases with severely dysplastic valves or after failed repair, mitral valve replacement (MVR) is the only option. Because valve repair is typically the initial objective of surgical therapy, most patients present for valve replacement after a failed attempt at valve repair. In this situation, therapeutic alternatives include further attempts at mitral valve repair, abandonment of the left ventricle with atrial septectomy and a Damus–Kaye–Stancel–type anastomosis, or transplantation. Important considerations in choosing among these therapeutic alternatives and MVR include estimates of early and late mortality, the likelihood of repeat valve replacement, and the incidence of late complications associated with prosthetic valve replacement in this age group. Hence, in this

cross-sectional study we sought to determine short-term to long-term outcomes of MV surgery in children undergoing surgery in our center from ۱۳۸۲-۱۴۰۰. The main aims of study is finding the predictors of MV surgery outcomes among children and providing an evidence for identifying the most durable with long survival .surgical option in Iranian children undergoing MV surgery	
In patients with congenital MV disease, reconstructive surgery is the primary goal. However, in cases with severely dysplastic valves or failed repair, MVR is the only option. Günther et al (8) analyzed, retrospectively, data of 35 patients younger than 6 years of age, who underwent MVR in Munich, Germany. Between 1974 and 1997, 35 children underwent MVR. The ages ranged from 2.7 months to 5.5 years (mean 1.9 ± 1.7 y) and body weight varied between 3.2 and 16.7 kg (mean 8.2 ± 4 kg). The main indication (57%) for MVR was severe MV insufficiency. Eighteen patients (51%) had undergone at least one previous reconstructive operation (mean 1.46 ± 1.86 y) before the MVR. In 29 cases (83%), mechanical prostheses were implanted. Six patients received a bioprosthesis. The size of the prostheses ranged between 14 and 27 mm. The overall hospital mortality was 17.1%, and decreased from 33% (1974–1985) to 11.5% (1986–1997). Seven children died late. Eight patients (23%) required 10 reoperations. Freedom from reoperation at 10 years was 50 ± 22 %. Valve-related complications were thrombo-embolism (n=2), hemorrhage (n=1), structural deterioration (n=3) and non-structural dysfunction (n=3). Follow-up is 96% complete, with a total of 122 patient-years (mean 4.2 ± 4.7). 86% of the patients were in New York Heart Association (NYHA) class I, 95% had sinus rhythm and 59% did not need medication. All survivors, except for those who received a bioprosthesis, were placed on a regimen of warfarin, aiming to maintain the International Normalized Ratio (INR) between 2.5 and 3.5. In one third of these children, self-management of oral anticoagulation was performed either by the patients or their parents. They concluded that MVR in small children carries a high risk. The long-term results were satisfying. After failed reconstructive surgery, or as a primary procedure, they preferred mechanical prostheses. They were well tolerated and the incidence	بررسی متون

of anticoagulation-related complications was low. In another multi-institutional study in USA, Caldarone and his colleagues (1) reported short- and long-term outcomes after prosthetic MVR in children aged <5 years from 45 centers, 1982 to 1999. MVR was performed 176 times on 139 patients. Median follow-up was 6.2 years (range 0 to 20 years, 96% complete). Age at initial MVR was 1.9±1.4 years. Complications after initial MVR included heart block requiring pacemaker (16%), endocarditis (6%), thrombosis (3%), and stroke (2%). Patient survival was as follows: 1 year, 79%; 5 years, 75%; and 10 years, 74%. Age-adjusted multivariable predictors of death include the presence of complete atrioventricular canal (hazard ratio [HR] 4.76, 95% confidence interval [CI] 1.59 to 14.30), Shone's syndrome (HR 3.68, 95% CI 1.14 to 11.89), and increased ratio of prosthetic valve size to patient weight (relative risk 1.77 per mm/kg increment, 95% CI 1.06 to 2.97). They concluded that early mortality after MVR can be predicted on the basis of diagnosis and the size/weight ratio, and .the late mortality is low

Uva et al (4) evaluated 20 patients less than 1 year of age who underwent operations for congenital MV disease in France between 1980 and 1993. Ten patients had congenital MV incompetence and 10 had congenital MV stenosis. Mean age was 6.6 ± 3.4 months and mean weight was 5.6 ± 1.5 kg. Atrioventricular canal defects, univentricular heart, class III/IV hypoplastic left heart syndrome, discordant atrioventricular and ventriculoarterial connections, and acquired MV disease were excluded. Indications for operation were intractable heart failure or severe pulmonary hypertension, or both. Associated lesions, present in 90% of the patients, had been corrected by a previous operation in seven. In congenital MV incompetence there was normal leaflet motion (n = 3), leaflet prolapse (n = 2), and restricted leaflet motion (n = 5). In congenital MV stenosis anatomic abnormalities were parachute mitral valve (n = 4), typical MV stenosis (n = 3), hammock MV (n = 2), and supra-mitral ring (n = 1). MV repair was initially performed in 19 patients and MVR in one with hammock valve. Concurrent repair of associated lesions was performed in 12 patients. The operative

mortality rate was zero. There were six early reoperations in five patients for MVR (n = 4), a second repair (n = 1), and prosthetic valve thrombectomy (n = 1). One late death occurred 9 months after valve replacement. Late reoperations for MVR (n = 2), aortic valve replacement (AVR) (n = 1), MV repair (n = 2), subaortic stenosis resection (n = 1), and second MVR (n = 1) were performed in five patients. Actuarial freedom from reoperation is 58.0 ± 11.3 (confidence limits 46.9 to 68.9) at 7 years. After a mean follow-up of 67.6 ± 42.8 months, 94% of living patients are in NYHA class I. Doppler echocardiographic studies among the 13 patients with a native MV show mitral incompetence of greater than moderate degree in one patient and no significant residual MV stenosis. Overall, six patients had mitral prosthetic valves with a mean trans-prosthetic gradient of 6.2 ± 3.7 mm Hg. These results show that surgical treatment for congenital MV disease in the first year of life can be performed with low mortality. Based on these data, the MV repair is a realistic goal in about 70% of patients and possibly more with increased experience. Reoperation rate is still high and is related to complexity of mitral lesions and associated anomalies, .but late functional results are encouraging

In a retrospective study, Lee et al (9) reported their 20-year experience of MV repair in Korean children between January 1988 and December 2007. Patients with atrioventricular septal defect, single ventricle or atrioventricular discordance were excluded. Median age was 2.3 years (2 months to 17.6 years), and 47 children (34%) were infants. MV regurgitation was predominant in 125 patients (90%), and 91 (73%) of these showed MR grade ≥3. MV stenosis was predominant in 14 patients (10%), and median mean pressure gradient across the MV was 9 mmHg (0–20 mm Hg). Associated cardiac lesions were present in 111 patients (80%) and were addressed concurrently in 105 patients. Various surgical techniques were used according to the functional and pathologic findings of MV. There was no early death. Median follow-up was 8 years (2 months to 20 years, 78% complete). Twenty-six patients required 29 MV re-operations, and 11 of these required MVR. At 15 years, freedom from MV re-operation and MVR was 77% and

90%, respectively. The diagnosis of MV stenosis and MV status on discharge (MV regurgitation grade ≥3 or MV stenosis gradient ≥10 mmHg) were significant risk factors for re-operation. There were three late deaths, and the overall survival was 97% at 15 years. Among 122 survivors with MV regurgitation, 102 patients (84%) underwent echocardiography during follow-up. The degree of MV regurgitation decreased significantly and only five patients showed MV regurgitation grade 3. Among 14 survivors with MV stenosis, eight patients (57%) underwent echocardiography during follow-up. The degree of MS decreased significantly and median MV stenosis gradient was 2.8 mmHg (0–10 mm Hg). All survivors remain in the NYHA class I or II. Accordingly, they concluded that MV repair in children showed excellent survival, acceptable re-operation rate and satisfactory valve function at long-term follow-up. Residual MV dysfunction was a significant risk factor for re-operation, but re-repair was successful in more than half of the .patients who underwent re-operation

In a USA-based study, Kadoba et al (7) evaluated 25 patients who underwent MVR in the first year of life for MV stenosis and MV regurgitation 1973 through 1987. The patients with MV stenosis included two with mitral arcade, two with supravalvular MV stenosis with hypoplastic MV, and one with parachute MV. Included in the group of patients with MV regurgitation were 12 with atrioventricular canal defect, six with chordal and leaflet defects, one with Marfan's syndrome, and one with bacterial endocarditis. In four patients the valves were placed in the left atrium in a supraannular location. There were nine operative (atrioventricular canal defect seven, mitral regurgitation two) and five late (atrioventricular canal defect four, mitral stenosis one) deaths, giving actuarial 1- and 5-year survival rates of 52% and 43%, respectively. All 6 patients with tissue valves died; the four with supraannular mitral valve replacement survived. Nine patients required re-operation for MVR due to prosthetic stenosis 5 to 69 (mean 30) months after the original MVR (one operative death). Because of improvements in repair of atrioventricular canal defect in infancy, the need for MVR at atrioventricular canal defect repair has decreased. Although valvuloplasty has been advocated for repair of congenital MV disease and is applicable in some infants with mitral regurgitation, MVR is frequently unavoidable for congenital MV disease and can now be accomplished at a low operative risk, even when the prosthesis has to be positioned supra-

.annularly

MV repair for rheumatic MV disease in children has become the preferred surgical modality. A MV ring is frequently used in the repair. A recently introduced biodegradable ring has shown promising results and allows for growth of the native annulus. A total of 220 children who underwent MV repair for rheumatic valve disease in Switzerland between January 1994 and March 2006 were evaluated (10). MV insufficiency was predominant in 198 patients (90%). Fifty-seven patients (26%) had associated aortic valve insufficiency and 51 (23%) had tricuspid valve insufficiency addressed during the same surgery. A MV ring was used in 213 patients (173 Carpentier-Edwards and 40 biodegradable rings). Ninety-two percent (202 of 220) were in NYHA class III to IV. Echocardiography was performed at 6 months and thereafter once yearly. There were no hospital deaths or major postoperative morbidity. Follow-up was complete in 96% (212 of 220). One late death occurred. Mean follow-up was 76.4 months (range, 1 to 13 years). One patient (0.5%) had immediate MV repair failure and required MVR. Twelve patients (5.5%) required reoperation during follow-up. Recurrent MV insufficiency/stenosis-free survival was 94.5% at 5 years and 92.7% at 10 years. Mean gradient was 5.2 ± 1.9, 6.2 ± 2.0, and 7.0 ± 2.3 mm Hg, respectively, at 7 days, 6 months, and 1 year postoperatively for the Carpentier-Edwards ring and significantly lower ($p < 0.001$) for the biodegradable ring at 2.8 ± 0.5, 3.1 ± 0.7, and 3.3 ± 0.5 mm Hg, respectively. Unchanged mean gradient during the first year was 65% (26 of 40) for the biodegradable ring and 21% (31 of 147) for the Carpentier-Edwards ring. Investigators concluded that MV repair in children with rheumatic valve disease has excellent immediate results with low operative risk and satisfactory midterm results and should therefore be the preferred treatment of choice. The use of biodegradable MV ring results in a significant lower mean gradient during the first year of implantation compared with the Carpentier-.Edwards ring and is available in a wide range of sizes

منابع

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اهداف: هدف اصلی، اهداف اختصاصی، هدف کاربردی

اهداف (خروجی ها) اصلی طرح[8]:

To evaluate short- to long-term outcomes of MV surgery in children

اهداف (خروجی ها) اختصاصی طرح[9] :

۱. Determining the predictors of outcomes of MV surgery in children

۲. Determining the predictors of MV surgery in children by the type of surgery, repair versus replacement

۳. Determining the outcomes of MV surgery in children by gender

۴. Determining the outcomes of MV surgery in children by the pathology of MV

۵. Determining the outcomes of MV surgery in children by the severity of MV regurgitation

۶. Determining the outcomes of MV surgery in children by the severity of MV stenosis

۷. Determining the outcomes of MV surgery in children by the presence of concomitant congenital heart disease

۸. Determining the outcomes of MV surgery in children by the type of implanted prosthetic valve, biologic versus mechanical

اهداف کاربردی طرح[10]:

۱. To identify the predictors of MV surgery outcomes among children in our population

۲. To provide an evidence for identifying the most durable with long survival surgical option in Iranian children undergoing MV surgery

فرضیات یا سوالات پژوهشی

۱. Which variables can predict outcomes of MV surgery in children?

۲. Which type of surgery, repair versus replacement, is associated with better outcomes of MV surgery in children?

۳. What is the association between gender and the outcomes of MV surgery in children?

۴. What is the association between MV pathology and the outcomes of MV surgery in children?

۵. What is the association between the severity of MV regurgitation and the outcomes of MV surgery in children?

۶. What is the association between the severity of MV stenosis

?and the outcomes of MV surgery in children

۷. What is the association between the presence of concomitant congenital heart disease and the outcomes of MV surgery in children with MV diseases?

۸. What is the association between the type of implanted prosthetic valve, biologic versus mechanical, and the outcomes of MV surgery in children with MV diseases?

روش اجرا

In a retrospective manner, we will review the medical files of Rajaie CMRC for finding data related to children who underwent MV surgery between 1382 and 1398. Data will comprise of baseline demographics, data on details of surgical features, and echocardiographic examinations of patients during visit to echocardiographic laboratory before surgery and during follow-up period. The duration of follow-up will be at least 6 months after first visit to our center.

Inclusion criteria include children <15 years old who underwent MV surgery in Rajaie CMRC.

Exclusion criteria include patients without complete data on surgical modalities and echocardiographic examinations as well as the lack of data on echocardiographic examinations during follow-up period after surgery.

:Statistical analysis will be as follows

According to the experience of the study investigators, the sample .size will be at least 2500 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 reviewing medical files of children who underwent MV surgery in Rajaie CMRC. All data will be entered into designed questionnaires and then those will be transferred into statistical software. Echocardiographic data at follow-up period will be extracted from electronic database of Rajaie CMRC. Moreover, the long-term outcomes will also be extracted from clinic visiting and telephone interview by parents .and/or patients
روش محاسبه حجم نمونه و تعدادآن	All available data in the hospital database will be evaluated and patients who underwent MV surgery associated with sufficient and reliable data will be entered into study. The number of sample size is estimated to be around 150 patients.
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 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
رکوردی یافت نشد									

زمانبندی و مراحل اجرا

شرح مختصر مرحله	درصد مرحله	مدت اجرا – ماه	از تاریخ	تا تاریخ
Medical file review and data collection		۱۲		

Data cleaning and data handling		۳		
Follow-up data collecting		۵		
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
گلنار مرتاض هجری(۱۸۸۶)	جمع آوری دیتا	۳۰,۰۰۰,۰۰۰
فروزان قربانی(۸)	وارد کردن دیتا	۳۰,۰۰۰,۰۰۰
یوسف مقدم(۴۳۱)	همکاری از بخش کامپیوتر	۲۰,۰۰۰,۰۰۰
شایان نقشبندی(۱۹۵۳)	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