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Early and long-term results of heart transplantation with reoperative sternotomy

Reoperatif sternotomi ile kalp naklinin erken ve geç dönem sonuçları

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ABSTRACT

Background: This study aims to investigate the effects of reoperative sternotomy on early and long-term outcomes after heart transplantation.

Methods: We retrospectively reviewed data of a total of 92 patients (72 males, 20 females; mean age 36 years; range, 3 to 61 years) who underwent orthotopic heart transplantation between May 1998 and July 2014. The patients were divided into three groups. Group A (n=23) included patients who underwent previous cardiac surgery with sternotomy other than ventricular assist device implantation; Group B (n=12) included patients who were bridged-to-transplant with a ventricular assist device; and Group C (n=57) included patients who for the first time underwent heart transplantation without previous sternotomy. Preoperative and operative data of the three groups were compared. The short- and long-term outcomes of all groups were analyzed.

Results: There was no significant difference among the groups, except for the age and preoperative international normalized ratio. Total ischemia time in the ventricular assist device group was longer than Group C. The length of intensive care unit stay was also longer in the ventricular assist device group than the other groups. The amount of postoperative chest tube drainage and blood transfusion was higher in Group A. Early mortality rate was significantly higher in Group A. There was no significant difference in survival among the three groups in the long-term. According to the logistic regression analysis, no variable was found to be a significant risk factor for mortality.

Conclusion: Reoperative sternotomy other than ventricular assist device implantation was found to be a risk factor for early mortality; however, mid and long-term survival rates were similar to patients in whom transplantation was the primary procedure. In patients with reoperative sternotomy, heart transplantation can be performed with similar risks to patients without resternotomy with careful selection and accurate pre- and intraoperative surgical approach.

Keywords: End-stage heart failure, heart transplantation, reoperative sternotomy.

ÖZ

Amaç: Bu çalışmada kalp nakli sonrasında reoperatif sternotominin erken ve geç dönem sonuçlar üzerine etkileri araştırıldı.

Çalışma planı: Mayıs 1998 - Temmuz 2014 tarihleri arasında ortotopik kalp nakli yapılan toplam 92 hastanın (72 erkek, 20 kadın; ort. yaş 36; dağılım, 3-61 yaş) verileri retrospektif olarak incelendi. Hastalar üç gruba ayrıldı. Grup A (n=23) daha önce ventrikül destek cihaz implantasyonu hariç sternotomi ile kalp ameliyatı geçirmiş olan hastalardan; Grup B (n=12) ventrikül destek cihazı ile kalp nakline köprülenen hastalardan ve Grup C (n=57) daha önce sternotomi yapılmayan ve ilk kez kalp ameliyatı yapılan hastalardan oluşuyordu. Üç grubun ameliyat öncesi ve ameliyat verileri karşılaştırıldı. Tüm grupların kısa ve uzun dönem sonuçları incelendi.

Bulgular: Gruplar arasında yaş ve ameliyat öncesi uluslararası normalleştirilmiş oran haricinde anlamlı bir fark yoktu. Toplam iskemi süresi, Grup C'ye kıyasla, ventrikül destek cihazı grubunda daha uzundu. Yoğun bakımda kalış süresi de, ventrikül destek cihazı grubunda diğer iki gruba kıyasla daha uzundu. Ameliyat sonrası göğüs tüpü drenaj ve kan transfüzyon miktarı, Grup A'da daha fazlaydı. Erken mortalite oranı Grup A'da anlamlı olarak daha yüksekti. Uzun dönemde üç grup arasında sağkalım açısından anlamlı bir fark yoktu. Lojistik regresyon analizine göre, değişkenlerin hiçbiri mortalitenin anlamlı bir risk faktörü değildi.

Sonuç: Ventrikül destek cihaz implantasyonu haricinde reoperatif sternotomi, erken mortalitenin bir risk faktörü olarak bulundu; ancak orta ve uzun dönem sağkalım oranları, naklin ilk işlem olduğu hastalar ile benzerdi. Reoperatif sternotomi hastalarında kalp nakli titiz bir seçim ve doğru ameliyat öncesi ve ameliyat sırası cerrahi yaklaşım ile resternotomi yapılmayan hastalara benzer riskler ile gerçekleştirilebilir.

Anahtar sözcükler: Son dönem kalp yetmezliği, kalp nakli, reoperatif sternotomi.

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Orthotopic heart transplantation (OHTx) is the treatment of choice in patients with end-stage heart failure (ESHF). Currently, the number of newly diagnosed patients with heart failure increases exponentially, and survival of these patients has been prolonged with sophisticated treatment modalities and widespread use of mechanical circulatory support in many settings.[1] Therefore, the number of transplant candidates having previous cardiac surgery has been increasing. Unfortunately, heart transplantation (HTx) only benefits to limited number of patients due to donor shortage.[2] This highlights the unmet need for the identification of various risk factors for early and late complications after HTx to stratify recipients most likely to benefit from surgery.[3]

Today, treatment modalities such as coronary artery bypass grafting (CABG), valve surgery, and ventricular assist device (VAD) implantation prior to HTx have been become widespread; however, some authors have suggested that previous cardiac operations are associated with poorer outcomes.[4,5] Adhesions and scar formation from previous surgeries may prolong operation time, increase blood loss necessitating blood transfusion, and increase allogenic antibody formation and postoperative acute and chronic rejection process. Additionally, changes on the vascular bed due to continuous flow may result in increased bleeding, and complexity of left ventricular assist device (LVAD) explantation may worsen outcomes after OHTx.

In this study, we aimed to evaluate the effects of reoperative sternotomy on early and long-term outcomes and to compare the survival among the recipients of OHTx.

PATIENTS AND METHODS

This single-center, retrospective study included a total of 92 patients (72 males, 20 females; mean age 36 years; range, 3 to 61 years) with ESHF who underwent OHTx between May 1998 and July 2014. The patients were divided into three groups. Group A (n=23) included patients who underwent previous cardiac surgery with sternotomy other than VAD implantation; Group B (n=12) included patients who were bridged-to-transplant with a VAD; and Group C (control group; n=57) included patients who for the first time underwent OHTx without previous sternotomy. Data including demographic characteristics, medical history, laboratory results, right heart catherization and echocardiographic data, surgical procedural details, and adverse events were collected. A written informed consent was obtained from each patient. The study protocol was approved by Türkiye Yüksek İhtisas Training and Research Hospital Ethics Committee. The study was conducted in accordance with the principles of the Declaration of Helsinki.

Right heart catheterization was performed in all patients. Pulmonary artery pressures and cardiac output were measured and pulmonary and systemic vascular resistances were calculated according to standard formulas. Hematological and biochemical measures including plasma urea, creatinine, complete blood count, and liver function were analyzed in all groups. Coagulation parameters were also recorded. Each patient was screened for human immunodeficiency virus, cytomegalovirus, and hepatitis A, B and C. Patient serum reactivity was tested using panel reactive antibody screening and values above 10% were considered positive.

Operative technique

St. Thomas solution was used as a cardioplegic solution for diastolic arrest in donor hearts until 2015. Since 2015, however, St. Thomas solution was replaced with the Bretschneider's HTK solution. All donor hearts were excised with an intact right atrium and long superior and inferior vena cava.

Standard median sternotomy was performed and cardiopulmonary bypass was established via aortic and bicaval cannulation at 28°C in patients in whom the HTx was the primary cardiac procedure (Group C). In Group A and B, after preliminary exposure of the femoral vessels, median resternotomy was performed. For patients with severe ventricular dysfunction, cardiogenic shock, and multiple prior sternotomies, femoral cannulation and cardiopulmonary bypass was instituted before median sternotomy. After cross-clamping, bicaval anastomotic technique was adopted as the standard technique for all patients. The left atrial cuff, aorta, main pulmonary artery, and superior and inferior vena cava end-to-end anastomoses were performed in order.

Postoperative management

In the early postoperative period, positive inotropes were needed in all patients. Immunosuppressive agents, prophylactic antimicrobials, and oral/inhaled pulmonary vasodilators were initiated as soon as possible after OHTx. Mechanical assist was used when clinically indicated. Intensive care unit (ICU) and total hospitalization length, duration of mechanical ventilation, and amount of postoperative blood loss were recorded. Routine blood tests (i.e., liver and kidney function, coagulation parameters, and complete blood count) were evaluated on a daily basis and blood bacterial cultures were evaluated on a weekly basis in all patients.

Table 1. Previous cardiac surgeries of patients

Prior surgery	n
Coronary artery bypass grafting	11
Cardiomyoplasty	5
MVR	3
AVR, MVR	1
AVR, MVR, graft replacement of ascending aorta	1
Left ventricular assist device	8
Biventricular assist device	2
Total heart	2
Congenital surgery	2
Total	35

MVR: Mitral valve replacement; AVR: Aortic valve replacement.

Immunosuppression

A dose of 20 mg of basiliximab for induction therapy was used just prior to sternotomy. Before de-clamping, 500 mg methylprednisolone was intravenously administered. Postoperatively, all patients received methylprednisolone 125 mg t.i.d. intravenously for the first postoperative day. Triple immunosuppressive therapy for maintenance was the standard regimen for all patients, containing oral prednisolone initiated after extubation at a dose of 1 mg/kg and tapered slowly down to 0.1 mg/kg at the first year. Mycophenolate mofetil and cyclosporine A were the other two drugs of the regimen. In case of severe renal dysfunction, cyclosporine was replaced with everolimus.

Endomyocardial biopsy

Endomyocardial biopsy was performed routinely at the second and fourth postoperative weeks, and at 3, 6, and 12 months, thereafter. In case of suspected rejection during routine outpatient follow-up, supplementary biopsies were performed.

Statistical analysis

Statistical analysis was performed using the SPSS version 15.0 software (SPSS Inc., Chicago, IL, USA). The variables were investigated using visual (histograms, probability plots) and analytical methods (Kolmogorov-Smirnov/Shapiro-Wilk test) to determine the normality of their distribution. Continuous variables were expressed in mean ± standard deviation (SD) and median (min-max or interquartile range [IQR], while categorical variables were expressed in number and frequency. Demographic characteristics and perioperative variables were compared using the one-way analysis of variance (ANOVA) for continuous variables and the chi-square test of homogeneity for categorical variables. Survival was calculated using the Kaplan-Meier method and survival comparisons were performed using the log-rank test. Logistic regression was used to identify the independent factors associated with mortality. A two-tailed p value of <0.05 was considered statistically significant.

RESULTS

In Group A, 20 patients were males with a mean age of 41.4±12.6 years. Eleven patients had ischemic

Table 2. The basic demographic data of the three groups of patients

	Group A (n=23)		Group B (n=12)		Group C (n=57)		
	%	Mean±SD	%	Mean±SD	%	Mean±SD	p
Age (year)		41.4±12.6		27.4±9.8		35.8±15.1	0.022
Gender							0.38
Male	87		83		74		
Female	13		17		26		
Weight (kg)		72.1±17.6		65±17.4		60.5±20.9	0.10
Aetiology							0.08
Non-ischemic	52		92		84		
Ischemic	48		8		16		
Donor age		27.8±10.7		29.8±9.6		27.5±11.5	0.85
Donor gender							0.62
Male	81		33		72		
Female	19		67		28		

SD: Standard deviation.

Table 3. Preoperative data in patients of the three groups

	Group A (n=23)		Group B (n=12)		Group C (n=57)		
	n	Mean±SD	n	Mean±SD	n	Mean±SD	*p*
NYHA functional status							0.051
Class II	0		2		2		
Class III	3		2		2		
Class IV	20		8		53		
UNOS status							0.08
I	10		8		27		
II	13		4		30		
LVEF		22.4±8.9		16.2±6.7		22.7±10.1	0.09
Pulmonary vascular resistance		3.0±0.9		3.2±0.8		2.7±0.8	0.22
SPAP		46.1±7.1		37.5±13.0		42±9.3	0.06
Duration on waiting list (months)		9.1±7.5		7.6±5.1		6.8±7.0	0.49
Preoperative INR		1.8±0.6		2.2±0.5		1.4±0.2	<0.001
Preoperative BUN		64.5±37.1		55.4±43.0		49.8±29.7	0.37
Preoperative creatinine		1.2±0.4		1.2±0.7		0.9±0.4	0.12
Preoperative GFR		85.8±24.6		106.8±49.3		90.8±5	0.42

SD: Standard deviation; NYHA: New-York Heart Association; UNOS: United Network for Organ Sharing; LVEF: Left ventricular ejection fraction; SPAP: Systolic pulmonary artery pressure; INR: International normalized ratio; BUN: Blood urea-nitrogen; GFR: Glomerular filtration rate.

cardiomyopathy. Previous cardiac operations included CABG in 11, cardiomyoplasty in five, mitral valve replacement (MVR) in three, aortic valve replacement (AVR) + MVR in one, AVR + MVR + graft replacement of the ascending aorta in one, and congenital cardiac surgery in two patients (Table 1).

In Group B, 10 patients were males with a mean age of 27.4±9.8 years. Previous operations involved eight LVAD, two biventricular assist device, and two total artificial heart implantation.

In Group C, 42 were males with a mean age of 35.8±15.1 years. Forty-eight patients had non-ischemic cardiomyopathy, while nine had ischemic heart disease.

Baseline characteristics of the patients among three groups were similar (Table 2). The mean time on waiting list was 7.5±6.8 months and the mean postoperative follow-up was 46.2±48.3 months. Preoperative international normalized ratio (INR) values were significantly higher in Group B (2.2±0.5) than Group A (1.8±0.6) and the lowest in Group C (1.4±0.2) ($p<0.001$) (Table 3).

The mean graft ischemic time was significantly higher in Group B (231.3±25.8 min), compared to

Table 4. Perioperative data of patients in three groups

	Group A (n=23)		Group B (n=12)		Group C (n=57)		
	n	Mean±SD	n	Mean±SD	n	Mean±SD	*p*
Ischemia time (min)		205±46.7		231.3±25.8		195±43.4	0.028
Cross-clamp time (min)		87.2±22.4		86.2±25.9		83.6±20.0	0.59
CPB time (min)		202.6±80.5		191.6±70.1		167.8±67.9	0.13
ICU stay (days)		6.7±7		13.5±14.9		5.2±3.8	0.001
Hospital stay (days)		27.4±16.7		35±16.3		32.0±11.8	0.24
Drainage (cc)		2625±205		2024±1755		1444±1300	0.03
Volume of blood transfusion (cc)		1210±1433		1235±1266		600.9±449	0.025
Postoperative exploratory sternotomy	7		3		7		0.137
Early mortality	6		1		2		0.009

SD: Standard deviation; CPB: Cardiopulmonary bypass; ICU: Intensive care unit.

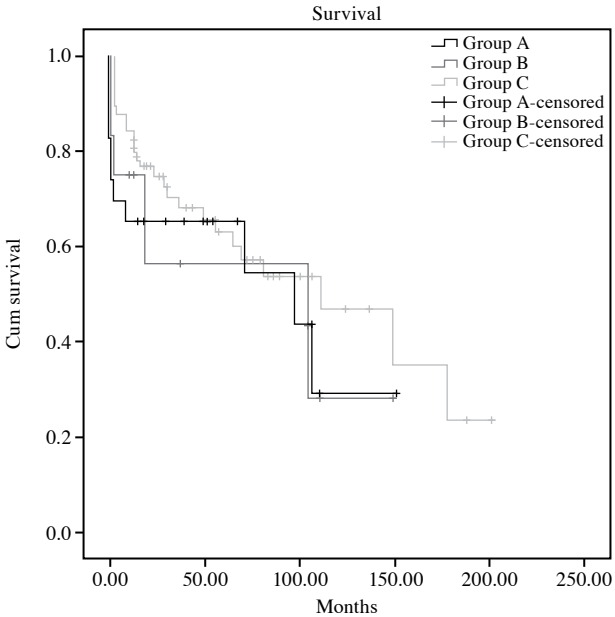

Figure 1. Kaplan-Meier survival curves of the patients in three groups.

Table 5. Analysis of factors for survival

	OR	%95 CI	*p*
Age	0.95	0.84-1.06	0.37
Weight	0.98	0.90-1.06	0.64
Gender	1.05	0.1-11	0.96
Donor age	1.11	0.996-1.25	0.059
Donor gender	1.16	0.08-15.4	0.91
PVR	1.34	0.6-12.1	0.181
Ischemia time	0.98	0.95-1.01	0.154
Cross-clamp time	0.94	0.87-1.02	0.12
CPB	1.02	0.98-1.06	0.28
Inotrope duration	1.06	0.94-1.18	0.35
ICU stay	1.03	0.61-1.72	0.91
Drainage	0.99	0.99-1.00	0.27
Blood transfusion	1.001	0.998-1.003	0.59
Exploratory sternotomy	0.092	0.001-8.71	0.30
Prior sternotomy	0.235	0.034-1.65	0.145

OR: Odds ratio; CI: Confidence interval; PVR: Pulmonary vascular resistance; CPB: Cardiopulmonary bypass; ICU: Intensive care unit.

Group C (195±43.4 min) (p=0.001), but not significantly different than Group A. The mean length of ICU stay was longer in Group B than Groups A and C (13.5±14.9 days vs. 6.7±7 days and 5.2±3.8, respectively p=0.047); however, the mean length of hospital stay was similar among the three groups.

The amount of intra- and postoperative chest tube drainage and blood transfusion was significantly higher in Group A than both Groups B and group C (drainage: 2625±2051 mL vs. 2024±1755 mL vs. 1444±1300 mL, respectively; p=0.03) (Table 4).

There were six (26%) early mortalities in Group A, which was significantly higher than one (8%) in Group B and two (3%) in Group B (p=0.009). Four patients had primary graft dysfunction, three patients had sepsis, and two patients had coagulopathy resulting in severe bleeding and multi-organ failure.

The median survival time was 101.2 months for Group A, 102.54 months for Group B, and 106.7 months for Group C. Survival at one, two, and five years were 65%, 65%, and 55% for Group A; 75%, 75%, and 56% for Group B, and 82%, 75%, and 63% for Group C, respectively (log-rank p=0.57) (Figure 1). According to logistic regression, no single variable was found to be significant risk factor for mortality and predictor of survival (Table 5). There was no significant difference among the three groups at early and long-term results in terms of rejection. A total of 298 endomyocardial biopsies were performed, and 24 (8%) biopsies revealed Grade 2R or 3R rejection requiring an additional treatment. After 2010, biopsies were evaluated for antibody-mediated rejection, and 11 of them revealed antibody mediated rejection and patients were treated according to standard protocols (Table 6).

Table 6. Comparison of endomyocardial biopsies among three groups

	Group A	Group B	Group C	Total	*p*
Grade 0R	28	13	86	127	0.3
Grade 1R	41	13	93	147	0.71
Grade 2R	3	4	16	23	0.64
Grade 3R	1	0	0	1	-
AMR 1	3	3	5	11	0.31

AMR: Antibody-mediated rejection.

DISCUSSION

The HTx is the gold standard treatment in patients with ESHF. The number of patients diagnosed with heart failure increases every year and the life expectancy is prolonged owing to the progress in medical treatment. However, inadequate number of donors causes loss of patients. To prolong the life expectancy of the patients on the waiting list and to reduce end-organ damage until HTx, mechanical circulatory support devices have been widely used. Therefore, the growing number of patients who have prolonged survival with mechanical support and who undergo previous cardiac procedures increases the percentage of reoperative HTx candidates. The effect of previous cardiac surgery and other characteristics of patients on survival after HTx has become a sought-after question in recent years.

In this single-center study, VAD patients were bridged to transplant mainly in the last decade and surgery of patients with VAD is associated with longer graft ischemic time, probably due to increased procurement of hearts from more distant centers in the last decade using more widespread airway transportation. This finding is supported with similar cardiopulmonary bypass and cross-clamp times among the three groups.

The recipient procedure of patients with previous sternotomy requires careful dissection of dense pericardial adhesions and is technically challenging, resulting in prolonged operative time. In addition, patients with VADs and mechanical valve prostheses have higher INR due to the use of coumarin which is associated with increased postoperative blood loss and transfusion.[6] Rigorous surgical approach to minimize injury to mediastinal structures would decrease the bleeding and blood product usage in this circumstance. Early start of recipient procedure would also prevent rushed dissection and probably decrease inadvertent injury to the mediastinal structures requiring excessive transfusion. In the randomized Transfusion Requirements After Cardiac Surgery (TRACS) study, irrespective of the treatment strategy, patients who received a red blood cell (RBC) transfusion had a higher rate of complications after surgery, including 30-day mortality.[6] The number of transfused RBC units was a predictive factor for 30-day mortality. Despite the increased use of blood products in the patients with previous sternotomies, there was no significant correlation between mortality and blood transfusion in our study. Aziz et al.[7] reported an increase in the amount of postoperative blood loss and exploratory sternotomy in patients with prior sternotomies after HTx.[7] In our study, there was no significant difference among the groups in terms of the number of exploratory sternotomies; however, Group A had significantly higher drainage and blood transfusion than Group C. Group B had non-significantly more drainage than Group C and the amount of blood products transfused was significantly higher in Group B than Group C. This finding suggests an increased early mortality in Group A due to more bleeding and transfusion, which we were unable to support with a non-significant effect of bleeding and transfusion in the logistic regression analysis.

Several reports demonstrated an association between previous sternotomy and increased mortality after HTx. George et al.[5] observed decreased survival rates at three months, one year, and five years. Awad et al.[8] also demonstrated decreased survival at one year among patients with prior sternotomies Vijayanagar et al.[9] found a similar significant decrease of survival in patients with prior sternotomies. However, current literature on the impact of reoperative sternotomy on mortality and survival is controversial. Carrel et al.[10] and Aziz et al.[7] reported similar survival rates between patients with prior cardiac surgeries and patients who underwent OHTx as the primary cardiac surgery. Kansara et al.[11] found that previous sternotomy was associated with a higher 90-day mortality rate; however, there was no significant difference at five years. Kokkinos et al.[12] reported similar survival outcomes between two groups at one, two, and five years. Different studies by Handa,[13] Ott,[14] and Lammermeier[15] also revealed similar results. In our study, early mortality was higher in Group A; however, survival rates at one, two, and five years were similar. This finding suggests that increased perioperative complications such as bleeding in patients with previous sternotomy affected early in-hospital survival; however, the difference among the groups reduced over time.

Although blood transfusion and LVAD implantation have been associated with allosensitization, which is a risk factor of previous cardiac surgery for rejection, our study did not yield such a result. Among 298 biopsies, only 8% of the patients had rejection and reoperative sternotomy was not found to be a significant risk factor. This finding indicates similar survival rates among the three groups. Furthermore, Özatik et al.[16] investigated factors affecting long-term survival in their study and they found that donor age influenced survival; however, there was no significant association in our study. In a report

by Patlolla et al.,[17] extracorporeal VADs were found to be associated with higher mortality rates within six months and beyond five years after transplant; however, in our study, the Kaplan-Meier survival analysis after OHTx between the patients with and without a VAD, indicating no statistically significant difference. Among the patients with prior sternotomy, OHTx may possess risks such as bleeding, long operation time, increased allosensitization, and rejection. These risks have an impact on early mortality which have been shown in several studies; however, patient selection and management improves outcomes and survival in course of time. Nonetheless, we believe that donor shortage and widespread use of mechanical circulatory support would eventuate, as the number of patients with prior sternotomies would continue to increase over time.

This study was not randomized and had the typical limitations of a retrospective analysis. In addition, it was a single-center experience; therefore, outcome interpretation is limited by institutional biases. Although reoperative sternotomy was not identified as an independent risk factor for survival in our study, we recommend further, large-scale, multi-center studies to establish a definite conclusion.

In conclusion, reoperative sternotomy other than ventricular assist device implantation was found to be a risk factor for early mortality; however, mid and long-term survival rates were similar to patients in whom transplantation was the primary procedure. In patients with reoperative sternotomy, heart transplantation can be performed with similar risks to patients without resternotomy with careful selection and accurate pre- and intraoperative surgical approach.

Declaration of conflicting interests

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