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Research Article

Baseline Characteristics and Clinical Outcomes of Patients with Autoimmune Diseases Undergoing Open Heart Surgery

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Abstract

Objectives: To investigate baseline characteristics and clinical outcomes in patients with autoimmune diseases (AID) undergoing open heart surgery.

Patients and Methods: A prospective cohort study was conducted over 3 years on 5,848 patients. Two hundred and four patients were included in the study: Group 1, n - 102 patients with AID and Group 2, n - 102 patients without AID. Patients were matched by propensity score based on: type of surgery, EuroSCORE II, gender, age, hypertension, diabetes mellitus, hyperlipidemia, previous myocardial infarction, acute coronary syndrome, and heredity. Demographic characteristics, risk factors, comorbidities and clinical outcomes (postoperative complications and infections), were monitored. The primary endpoints were: length of hospital stay, 1-month survival, and rehospitalization rate.

Results: Coronary artery bypass grafting (CABG) was the most common procedure (35%), valve surgery performed in 29% of cases, combined valve surgery + CABG in 20%, aortic surgery or congenital surgery in 13%, and simultaneous carotid artery endarterectomy with CABG in 2% of cases. There was no significant difference in postoperative complications between the two groups (41% vs. 48%; p = 0.114). The incidence of respiratory tract infections was significantly higher in patients with autoimmune diseases RR 0.146 (95% CI 0.033-0.649; p = 0.031). The median length of hospital stay was 17.0 days (range 12-23 vs. 13-24; p = 0.531). The mortality risk was RR 1.175 (95% CI 0.911-1.516; p = 0.464). During the follow-up period, the rehospitalization rate was RR 0.969 (95% CI 0.934-1.004; p = 0.830).

Conclusion: Most of the observed outcomes were without statistical differences, except for the incidence of respiratory tract infections. Despite chronic illness and possible disability, patients with autoimmune diseases adequately prepared before surgery have similar outcomes after open-heart surgery as patients with an unaffected immune system.

Keywords: Autoimmune Diseases; Cardiac Surgery; Clinical Outcomes

Introduction

A growing body of evidence suggests that the burden of autoimmune diseases (AID) has increased substantially; this includes reports from the National Institute of Health (NIH), [1] extended criteria reported by the American Autoimmune and Related Diseases Association (AARDA), [2] and several national registries in developed countries [3-6]. The incidence of these disorders appears to have began in the last fifty years with an alarming increase in mortality among young women [7-8]. Although the term "autoimmune diseases" may suggest homogeneity, the underlying disorders are very heterogeneous conditions that often lead to severe disability.

Patients who have chronic autoimmune disease frequently have cardiovascular complications and need for cardiac surgery. Scientific documentation is rare when it comes to clinical outcomes in this subset of patients. Published studies have been limited to one organ-specific autoimmune disease [9,10], to small sample sizes [11], or simple to reports isolated cases [12-14]. The purpose of this study was to analyze a large population of patients who underwent heart surgery, suffering concomitantly from chronic autoimmune diseases.

Patients and Methods

Study population

This cohort was conducted from October 15, 2015 to October 15, 2018 in tertiary care institution. The study design was approved by the Hospital Ethics Committee. The study included all patients with autoimmune diseases defined as a variety of conditions in which the host immune system attacks own antigens (classified according to the AARDA database).[2] After having signed the informed consent, 106 patients with AID were prospectively recruited. All patients were in stable condition before surgery; the recommendations regarding immunosuppressive therapy are controlled by an immunologist or rheumatologist. Four of 106 patients (3.7%) were excluded since, in the opinion of the team (cardiac surgeon, cardiologist, immunologist, anaesthesiologist, and radiologist), there was no possibility to improve patients' physical condition by surgical treatment. Further data in this paper refers only to the patients who underwent surgery. The European System for Cardiac Operative Risk Evaluation (EuroSCORE II) has been calculated for all patients prior to the surgery. At the same time, 102 patients without autoimmune disease were enrolled as a control group. They were registered from the hospital database. Patients were matched by propensity score taking in consideration: type of surgery, EuroSCORE II, gender, age, hypertension, diabetes mellitus, hyperlipidemia, previous myocardial infarction, acute coronary syndrome, and heredity. During the study period, out of 5,848 adults, 102 patients with chronic autoimmune diseases were enrolled in Group 1, and 102 patients without AID in Group 2.

Concerning the type of surgery, patients underwent: coronary artery bypass grafting (CABG); valve surgery (replacement or reconstruction); combined valve+CABG; complex cardiac surgery (aortic surgery, *redo* cardiac surgery) and carotid artery endarterectomy simultaneously with CABG. In the observed groups, the patient`s care did not differ from the usual standard care. Any change in the clinical status and course of the disease was registered in the patient's file. Clinical outcomes monitored were: complications and infections. Complications were classified by organs/systems: re-exploration for bleeding, cardiovascular events/arrhythmia, gastrointestinal disorders, neurological disorders, and renal failure. Infections were observed by systems such as: sternum/leg wound infections, respiratory tract infections, sepsis/blood infections, and urinary tract infections. Patients were monitored up to the 30th postoperative day, as well as 30 days after discharge. Primary endpoints were: length of hospital stay, 1-month survival, and rehospitalization rate. Rehospitalization rate was defined as 30-day all-cause readmissions related to the major diagnostic category.[15] Physicians were assigned to make phone calls 1 month after patient's release from hospital. Final cohort was completed on November 28, 2018.

Statistical analyses

Statistical analyses were performed using SPSS 18.0 software (SPSS, Chicago, IL). Categorical variables are presented as number (%) and continuous variables as mean value (± SD) when normally distributed or otherwise as a median with interquartile range (IQR). We used X^2 and Fisher's exact test to compare categorical variables and *t* test or Mann-Whitney U test to compare continuous variables. Mortality rate and patient survival were estimated using the Kaplan-Meier method; differences between the arms were compared using the univariate logistic regression. A 2-sided P value < 0.05 was considered statistically significant.

Results

Baseline patient`s characteristics and operative details

Among 5,848 consecutive surgical patients, 102 had autoimmune disease in this study.

The prevalence of autoimmune diseases was 1.8%. The main autoimmune diagnoses are specified in figure 1. As a final point, 75/102 (73%) patients suffered from one organ/system specific AID: rheumatoid arthritis (RA) 21%, systemic lupus erythematosus (SLE) 13%, Hashimoto thyroiditis (HT) 12%, psoriatic arthritis/psoriasis (PA) 10%, ulcerative colitis (UC) 6%, and diverse monospecific autoimmune diseases 13% (e.g. primary biliary cirrhosis, sarcoidosis, scleroderma/progressive sclerosis, Sjogren's disease, autoimmune haemolytic anaemia, Crohn's disease, polymyositis/dermatomyositis, antiphospholipid syndrome, Graves disease, ankylosing spondylitis, anemia pernicious); 17/102 (17%) patients suffered from two simultaneous AID; finally 10/102 (10%) patients had three or more organs/systems involved in autoimmune processes. Most patients in Group 1 were on immunosuppressive drugs (92/102). Before the surgical procedure, they were switched from oral to intravenous formulation of immunosuppressive medications.

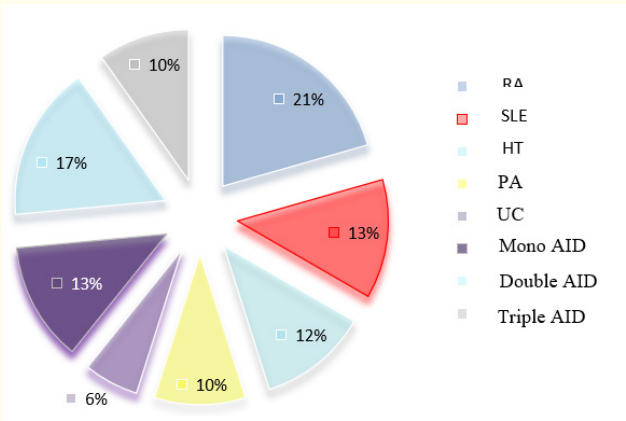

Figure 1: Spectrum of autoimmune diseases in patients subjected to open heart surgery.

Baseline characteristics of participants are presented in table 1. Their average age was 64 ± 11 (64.11 ± 10.23 vs. 64.0 ± 12.27%, p = 0.752) years; 107/204 (52%) were male. Patients did not differ much in their demographics, risk factors, and comorbidities, except for smoking history and prevalence of allergic diseases. Patients from control group had higher risk of smoking related diseases (14.7% vs. 26.4%, p = 0.038), whereas patients with autoimmune diseases had two times higher proportion of allergic manifestations (38.6% vs. 18.6%, p = 0.002).

Characteristics	Group 1	Group 2	p
n	102	102	
Age, y, m	65 (58-72)	67 (58-73.2)	0.752
Gender, male, n (%)	51 (50)	56 (54.9)	0.483
BMI, kg/m^2, m	27 (23-30)	26 (23-29)	0.624
LVEF, %, m	50 (46-60)	50 (46-55)	0.968
NYHA I, n (%)	12 (12)	4 (18.6)	0.055
NYHA II, n (%)	63 (63.2)	74 (57.9)	0.776
NYHA III, n (%)	25 (25)	24 (23.5)	0.566
NYHA IV, n (%)	2 (1.8)	0 (0)	0.239
Previous AMI, n (%)	22 (21.5)	26 (25.5)	0.509
Acute coronary syndrome, n (%)	3 (2.94)	1 (0.98)	0.313
Hypertension, n (%)	87 (85.3)	85 (84.3)	0.700
Diabetes, n (%)	27 (26.4)	29 (28.4)	0.754
Hyperlipidemia, n (%)	62 (60.7)	61 (59.8)	0.886
Family history, n (%)	55 (53.9)	51 (50)	0.575
Smoking, n (%)	15 (14.7)	27 (26.4) *	0.038
TIA, n (%)	43 (42.16)	32 (31.37)	0.110
Peripheral vascular disease, n (%)	21 (20.59)	13 (12.75)	0. 133
Allergy, n (%)	15 (38.61) *	4 (18.63)	0.002
EuroSCORE II, m	1.85 (1.20-3.43)	1.97 (1.33-3.77)	0.708

Table 1: Demographic characteristics, risk factors, and comorbidities after propensity score matching.

Legend: AMI: Acute Myocardial Infarction; BMI: Body Mass Index; Euro SCORE: European System for Cardiac Operative Risk Evaluation; LVEF: Left Ventricle Ejection Fraction; m: Median; n: Number; NYHA: New York Heart Association Classification; TIA: Transient Ischemic Attack; y: Year

Data are presented as number (percentage), or median with interquartile range [25% to 75%].

* p ≤ 0.05 was considered statistically significant.

In terms of surgical procedures, 72/204 (35%) patients underwent on-pump CABG, 60/204 (29%) valve replacement/reparation, 42/204 (20%) combined CABG and valve replacements, 26/204 (13%) aortic surgery (Bentall de Bono operation, David's reimplantation procedure), septal repair, or congenital surgery, and 4/204 (2%) simultaneous carotid artery endarterectomy with CABG (Figure 2). Most patients 196/204 (96.1%) underwent a de novo procedure, and 8/204 (3.9%) received a redo cardiac surgery.

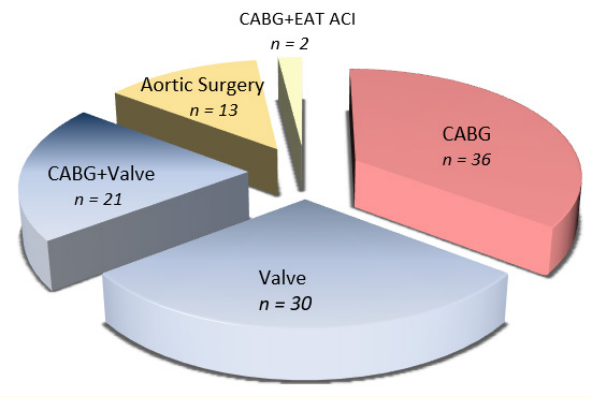

Figure 2: The type of surgery in one of the observed groups.

Postoperative patient`s characteristics and clinical outcomes

Table 2 shows data at the time of surgery and perioperative conditions. All patients were subjected to the elective surgical procedures, illustrated on figure 2. The operative data, cardiopulmonary bypass time, and aortic cross-clamp time was shorter in control patients, but we found no evidence of a difference between the groups. The volume of solution used for cardioprotection was equal in both groups, as well as duration of mechanical ventilation. Although long-lasting immunosuppressive therapy (especially corticosteroids) could lead to disturbances in coagulation/haemostasis process, there were not significant differences in blood loss or blood transfused during/after surgery. The mean stay at Intensive Care Unit (ICU) was 4.5 vs. 5.5 days (p = 0.765).

Postoperative clinical outcomes are presented in table 3. Overall percentage of complications in Group 1 was 41% vs. 48% (p = 0.114), while frequency of infections was 17.6% vs. 21.5% (p = 0.188). Most of the observed outcomes do not differ including

Characteristics	Group 1	Group 2	*p*-value
n	102	102	
Surgical procedure, n (%)			
CABG	36 (30.55)	36 (30.55)	0.999
Valve	30 (36.1)	30 (36.1)	0.999
CABG + Valve	21 (25)	21 (25)	0.999
Other[a]	15 (8.35)	15 (8.35)	0.999
CPB time, min, m	90 (66.5-116.5)	85 (69.7-120.7)	0.875
Aortic clamp, min, m	64 (49-81)	59 (46-83)	0.483
Cardioplegia, ml, m	1000 (800-1200)	1000 (870-1355)	0.669
Mechanical ventilation, h, m	14 (11-19)	14 (11-18)	0.605
RBC transfusion, ml, m	510 (290-815)	590 (420-1122)	0.116
Drainage, ml, m	500 (300-850)	500 (300-1800)	0.824
ICU stay, d, m	2 (2-5.25)	3 (2-7)	0.765
Postoperative hospital stays, d, m	8 (7-14)	8 (7-14.25)	0.432
Length of in-hospital stay, d, m	17 (12-23)	17 (13-24)	0.531

Table 2: Data at the time of surgery.

Legend: CABG: Coronary Artery Bypass Grafting; CPB: Cardiopulmonary Bypass; ICU: Intensive Care Unit; d: Days; h: Hours; m: Median; ml: Millilitre; min: Minute; n: Number; RBC: Red Blood Cells

[a] Aortic, atrial or ventricular septal repair, simultaneous, and congenital surgery

Data are presented as number and percentage or as median with IQR [interquartile range 25% to 75%].

* p ≤ 0.05 was considered statistically significant.

length of hospital stay, median 17.0 days (range: 12-23 vs. 13-24 days; p = 0.531). The exception was higher incidence of respiratory tract infections in patients with autoimmune disorders RR 0.146 (95%CI 0.033-0.649; p = 0.031).

During a follow-up period of 36 ± 1.5 months, 195/204 (95.5%) patients survived the first hospitalization (Figure 3). By the 30th postoperative day, the mortality rate was no statistically different RR 1.175 (95%CI 0.911-1.516; p = 0.464). All deceased patients were older than 70 years (75.2 ± 2.5 vs. 74.5 ± 2.4) and all under-

Condition	Group 1	Group 2	RR	*p*-value
n	102	102		
Death, n (%)	6 (5.9)	3 (2.9)	1.175 (0.911 - 1.516)	0.464
Complications (overall), n (%)	42 (41)	49 (48)	1.214 (1.039 - 1.419)	0.114
Re-exploration for bleeding, n (%)	6 (5.9)	7 (6.9)	0.275 (0.027 - 2.818)	0.247
Arrhythmia/CV events, n (%)	18 (17.6)	24 (23.5)	0.185 (0.034 - 1.006)	0.151
Gastrointestinal disorders, n (%)	1 (0.9)	2 (1.9)	0.969 (0.934 - 1.004)	0.330
Neurological disorders, n (%)	6 (5.9)	9 (8.8)	0.184 (0.015 - 2.257)	0.421
Renal failure, n (%)	6 (5.9)	2 (1.9)	0.135 (0.011 - 1.708)	0.147
Infections (overall), n (%)	18 (17.6)	22 (21.5)	1.234 (0.136 - 1.119)	0.188
Deep sternal/wound infections, n (%)	1 (0.9)	4 (3.9)	0.941 (0.896 - 0.988)	0.174
Respiratory tract infections, n (%)	12 (11.8) *	4 (3.9)	0.146 (0.033 - 0.649)	0.031
SIRS/sepsis, n (%)	5 (4.9)	6 (5.9)	0.939 (0.894 - 0.988)	0.757
Urinary tract infections, n (%)	1 (0.9)	2 (1.9)	1.234 (0.113 - 1.190)	0.152
Rehospitalization rate, n (%)	11 (13.7)	10 (12.6)	0.969 (0.934 - 1.004)	0.830

Table 3: Outcomes at 30 days follow-up.

Legend: CV: Cardiovascular; n: Number; RR: Relative Risk (95% CI), SIRS: Systemic Inflammatory Response

Data are presented as number and percentage.

* $p \leq 0.05$ was considered statistically significant.

went complex cardiac surgery: valve procedures or combine valve + CABG surgery. In Group 1 the most powerful predictors of mortality were: blood loss, blood transfusion, and intubation time X^2 (27.09, df - 21, N = 102), $p > 0.05$. In the control group dominated: hypertension and diabetes mellitus. The only independent predictor of mortality was diabetes mellitus X^2 (13.12, df - 2, N = 102), $p < 0.0001$. Rehospitalization rate was only 1.1% higher in AID patients RR 0.969 (95%CI 0.934-1.004; p=0.830), but the number of days after re-admission was 4.65-fold higher in patients with autoimmune diseases (349 ± 18 vs. 92 ± 3 days; p=0.002).

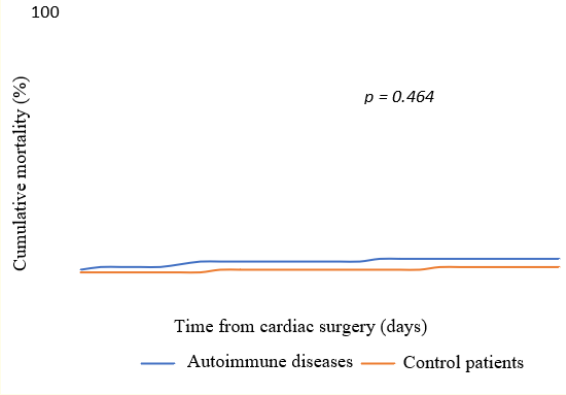

Figure 3: Mortality rate within 1st month after surgery.

Discussion

Since the end of World War II, an alarming increase in autoimmune diseases has been registered around the world. In the United States (US), the actual number of persons affected by autoimmune diseases is unknown. The exact number remains controversial with an NIH estimate of 23.5 million patients, meaning that one in five people suffer from AID [1] AARDA [2] estimates this number is twice as high because it recognizes over 80 diagnoses of autoimmune diseases compared to only 24 listed by NIH [4,6]. Autoimmune diseases present the top 10 causes of death in girls and women under the age of 64 [8]. According to Walsh a significant number of diseased patients were not recognized in the US since Specific International Disease Categories Identification/Code is not available for many autoimmune diseases. Consequently, it is very difficult for epidemiologists to count AID deaths with high accuracy [8]. Epidemiologists confirmed that the importance of auto-

immune diseases has been underestimated and neglected globally. Thomas and co-workers concluded that their collective impact remains hidden in current disease classification systems in England and Wales, also [16].

In the same time, the cardiovascular diseases are the leading cause of death in the developed countries [17]. Heart surgery is associated with substantial morbidity, high mortality rate, and elevated financial expenditure. Speir., *et al*. [18]. showed that complications after open-heart surgery result in a prolonged hospital stay and greater financial costs. The scientific papers are extremely rare concerning the patients affected by autoimmune diseases subjected to open-heart surgery. Some papers described a surgical protocols, exceptionally performed and its clinical outcomes [12,14]. another depict the cases where cardiac surgery trigger autoimmune processes [11,13,19,20]. All of them exemplify small series.

Sleeman., *et al*. [11] described the onset of myasthenia gravis in three adult patients following cardiac surgery. Sternotomy can cause damage to thymus and trigger myasthenia gravis in adult individuals as well as in infants [11,19]. A study conducted for 23 years by Swedish authors [19] indicates that the new onset of autoimmune disease after cardiac surgery is not just a sporadic case. In a population of 5,664 infants, early sternotomy was recognized to trigger multiple autoimmune diseases (hypothirosis, celiac disease, juvenile idiopathic arthritis, diabetes type 1, or rheumatic diseases). Cardiac surgery is responsible for the autoimmune response and the *de novo* onset of Guillain-Barre syndrome (GBS), Cingoz and colleagues stated [20]. Based on a review of the literature, Iranian authors [13] investigated the association between GBS and cardiac surgery. They found 6 cases, first published in 1987. The beginning was recorded even 12 months after surgery.

Birdas., *et al*. [21] discussed outcomes in patients with connective tissue diseases and CABG. They identified 44 patients out of a total of 5,496 cases over a 7-years study period. As far as we know, the only article describing the long-term examination of patients with inflammatory rheumatic disease and clinical outcomes after CABG was published by Lai., *et al*. [22] Among the 40,639 adult patients who underwent first-time coronary artery bypass grafting between 2000 and 2010, 101 patients with RA, 56 with SLE, and 73 with ankylosing spondylitis were identified. The authors concluded that the limited surgical experience in any single center was probably due to the rarity of this particular patient population. Yazdanyar and co-workers [23] analyzed perioperative mortality and cardiovascular (CV) events in almost 8 million patients with RA and diabetes mellitus, but in noncardiac surgery. Nevertheless, their study declared an important conclusion: RA was not associated with adverse perioperative CV risk or mortality rate, which suggests that perioperative clinical care does not need to be changed in this subpopulation of patients.

We analyzed a wide spectrum of autoimmune diseases and the results are in concordance with Lai`s [22] and Yazdanyar`s [23] conclusions. Our research points to several important findings. First, the prevalence of autoimmune diseases was 1.8%. Second, the number of operated male and female patients was the same. Third, patients with autoimmune diseases have twice as many allergic manifestations at the baseline.

Regarding the autoimmune diseases, Cooper [4] and Parks [6] found that the prevalence ranges from 5.3% to 9.4% in the general population. In 2005, Birdas., *et al*. [21] estimated the prevalence of 0.8% in patients subjected to CABG. This increase from 0.8% to 1.8% (registered in our cohort) suggests that substantial progress has been made in the surgical treatment of patients with autoimmune diseases in the last decades.

The patients observed in our study were vigilantly matched. Comparing demographic characteristics there was no significant difference between two groups. Interestingly, the number of female patients was equal to that of male patients (48% *vs.* 52%), although autoimmune diseases often run in families and 75 percent of those are women [2,5,8]. The reasons for such discrepancies could be found in social and traditional style of life. Three decades ago, the biophysical and psychophysical profiles of men and women were shown to be different, suggesting that women have poorer postoperative recovery and a negative attitude to cardiac surgery [24,25]. It is also possible that some of the young and middle-aged woman with autoimmune disorders could not face cardiac surgery, as Walsh [8] and Thomas [16] claimed.

Comparing comorbidities, patients with autoimmune diseases had two times higher proportion of allergic manifestations (38% vs. 18%, p = 0.002). In fact, our study provokes the question: are autoimmune diseases associated with allergic manifestations? The

contemporary investigations have shown that there is one set of genes dominant over everything else, which is a huge determining factor for developing autoimmune diseases [2,26]. However, it is not the case with allergic diseases. There is no single gene or gene family which could be point out at as a gene responsible for allergic reaction. Nevertheless, research undertaken from 2013 has shown that people having minor variations in the Bach2 gene often develop allergic or autoimmune diseases, and that a common factor for both is a compromised immune system [26].

Look upon the risk factors, smoking habit was elevated in control group (14% vs. 26%, p = 0.03), but it was not associated with significant changes in operative variables, intubation time, or ICU stay. Perioperative outcomes showed an identical trend. Actually, we observed slightly higher incidence of complications (41% vs. 48%, p = 0.11) and infections (17% vs. 21%, p = 0.18) in patients with normal immune response. However, only the incidence of respiratory tract infections reached statistical significance in patients with autoimmune disease (12% vs. 4%, p = 0.03). This could be explained by the fact that the patients on immunomodulatory therapy are more susceptible to infectious agents. The elderly with allergic and/or atopic configuration, are predisposed to respiratory distress syndrome [19,21]. After an adequate antibiotic regimen, patients with AID did not stay an hospital longer. Postoperative and total hospital stay was analogous.

There was no significant difference between the two groups in terms of survival (94.1% and 97.1%, p = 0.46), which is consistent with other studies [21,22,27-29]. In a study conducted by Vogt., *et al*. [27] operative mortality ranged from 0.9% to 10.7%. Lai., *et al*. [22] specified that mortality was between 3.0% and 8.9% depending on the main diagnosis. The risk of mortality is higher in older adults [25,28] and all deceased patients in our study were older than 70 years. Moreover, all patients who died underwent valve repair or complex cardiac surgery.

A relatively small number of patients has been readmitted to our hospital, but the number of hospital days after readmission was four times higher in patients with autoimmune diseases. In recent years, reducing the readmission rate is the focus of a broad scientific society [30]. There is limited information concerning the frequency of rehospitalization rate worldwide, but 25% of all readmissions are occurring within 30 days after discharge [15,31]. Some authors suggested that the cause of readmission should be analyzed as a benchmark of quality of care [31]. Several authors point out that they do not have access to all data, given that 20 - 40% of their patients are rehospitalized in different hospitals [15]. We also encountered this problem because one in five patients provided unreliable data regarding on the number of re-admissions in other places. The limitation of this study lies in the fact that we have accurate data only from our hospital. Although re-admission refers to the main diagnostic category, we are aware that a follow-up period of 13 months, shown in our study, can result in confusing reports. Some researchers have argued that the total number of re-admissions after cardiac surgery is difficult to calculate due to a lack of community support and other specific reasons [30] Hannan., *et al*. [15] concluded that medical care should be aimed at reducing unnecessary rehospitalization. However, the aspiration is to introduce cardiac rehabilitation after discharge, which would improve early identification and treatment of complications.

Conclusions

Despite chronic illness and possible disability, patients with autoimmune diseases adequately prepared before surgery have similar outcomes after open-heart surgery as patients with an unaffected immune system. Today, immunosuppressive therapy can be adjusted to improve the patient`s condition before surgery. Patients with chronic autoimmune diseases did not stay in the hospital longer compared to the patients with a normal immune response. There was no significant difference in mortality rate or rehospitalization rate. In fact, the period for resolving complications after readmission could be longer in patients affected by autoimmune disorders.

Declaration

Conflicting Interest

The authors certify that there is no conflict of interest with any financial organization regarding the material discussed in the manuscript.

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