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Original Article

Health outcomes of on-pump pulmonary valve replacement surgery with and without cardioplegic arrest: a comparison study in tetralogy of Fallot subjects

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Abstract: Background: Tetralogy of Fallot is one of the most common congenital heart diseases in which four important cardiovascular defects. Pulmonary valve regurgitation (PVR) after TOF surgery is one of the indications for its replacement which is carried out with two surgical methods, on-pump surgery with and without cardiac arrest. Objective: The aim of this study was to compare the results of the pulmonary valve replacement surgery with and without cardiac arrest. Materials and methods: In this retrospective study, the information of medical records of all patients with TOF that candidates for pulmonary valve replacement from 2008 to 2014, whom treated in Kermanshah's Imam Ali cardiac hospital, Kermanshah. Iran and Shaheed Rajaei Heart Center in Tehran with the two common surgical procedure, with and without cardiac arrest, were studied. With matching for age and sex, 33 patients enrolled in this study, 16 patients underwent surgery with the arrest (in Kermanshah's Imam Ali cardiac hospital, Kermanshah. Iran) and 17 subjects operated without cardiac arrest (on pump beating heart in Shaheed Rajaei Heart Center in Tehran). Results: The results of this study showed that patients operated using without cardiac arrest compared to the with cardiac arrest, were superior in the hospital and ICU stay, bleeding until 24 hours after surgery, intubated time, inotropic support, and duration of surgery ($P<0.05$). Also, hemoglobin, blood pressure, ejection fraction (EF), and tricuspid regurgitation after surgery were statistically significant difference between two groups ($P<0.05$). Conclusion: The results of this study showed that although during the (on pump beating heart without aortic cross clamp) without cardiac arrest surgery method some problems may be created for the surgeon, nevertheless, patients after without arrested procedure have a better outcomes compared to the cardiac arrest method.

Keywords: Pulmonary valve regurgitation, tetralogy of Fallot, congenital heart disease, cardiopulmonary bypass, pulmonary valve replacement

Introduction

Tetralogy of Fallot (TOF) is the most common congenital heart diseases [1, 2], which include about 10 percent of all congenital heart anomalies and characterized by the onset of cyanosis in the first months of life [3]. TOF occurs about in 400 people per million live births and the clinical symptoms of this disorder include cyanosis, clubbing, dyspnea during exercise and hyper-cyanotic attacks [4, 5]. Treatment of this condition commonly is done at age 6 to 12 months by surgical procedure [6]. Overall this condition as a disease is not fatal, but if not treated, the mortality rate of patients up to the age of 40 is about 95 percent [7]. Recent advances in the diagnosis and treatment of these disorder has led to a large number of these patients reach puberty [8]. All together, the mortality rate in these patients, due to the development of medical and surgical procedures, about 40 percent decreased [9].

Several surgical techniques for these patients with low mortality and very little early complications are available, but also, delayed complications of these surgical procedures in such patients are life-threatening [10, 11]. Usually,

complications and adverse consequences of this disease in the long term is due to progressive pulmonary valve regurgitation [12, 13].

Pulmonary valve regurgitation (PVR), a common complication, particularly in patients who used the trans-annular patch in their surgical procedure [6]. The use of transannular patch for the resolving pulmonary artery stenosis and reconstruction of the right ventricular outflow tract, as a common method for the repair of TOF, led to PVR over the time [14]. In these patients, the risk of fatal cardiac arrhythmias and sudden death is high, these risks are frequently seen in patients with an increased QRS time [1]. Fatigue, dyspnea, ventricular arrhythmias and tricuspid regurgitation in patients with TOF with pulmonary valve insufficiency must be immediately considered for surgery again. In these patients [11, 15]. The placement of a biological or mechanical pulmonary valve could increase the right ventricle ejection fraction, decrease the right ventricular end-diastolic dimension and improve the symptomatic condition [16, 17]. On-pump cardiopulmonary bypass (CPB) valve replacement with cardiac arrest surgery, is a classic method that widely used. In this way stops the heart and lungs temporarily and surgeon take action to replace the pulmonary valve [18]. Ischemia-reperfusion is a complication that caused by cardiac arrest and subsequent to cardioplegic solution that may be reversible or irreversible which differentiated by abnormal electrocardiogram and an increase in plasma levels cardiac enzymes [19, 20].

In total, followed by the use of CPB and cardiac arrest, the patient may experience some complications such as tissue damage in various organs, micro embolism, and etc. [14, 21]. Another new surgery method is beating on pump (on pump without arrest). In this way, pump has been used, but during the operation, but the mechanical and electrical activity of heart will not disappear.

In recent years, the on pump beating heart technique have become widespread [22], but up to now, some surgeons still go through the on-pump with cardiac arrest procedure.

Objectives

The aim of this study was to compare the physiological state of patients in on-pump pulmonary valve replacement surgery with and without cardioplegic arrest procedures, following-up results in patients and identifies the advantages and disadvantages of these two methods.

Methods

In this study, the information of medical records of all patients with TOF that candidates for pulmonary valve replacement from 2008 to 2014, whom treated in Kermanshah's Imam Ali cardiac hospital and Shaheed Rajaei Heart Center in Tehran with the two common surgical procedure, with and without cardiac arrest (on pump beating heart), based on available sampling method have been studied. With matching for EF, underlying disease and demographic characteristics, 33 patients enrolled in this study, 16 patients underwent surgery with the arrest and 17 peoples operated without cardiac arrest. In the following, with a full review of patient's medical records, variables of interest like age, sex, previous surgery date, current surgery date, duration of surgery, ICU and hospital stay, require of blood products during and after surgery, valve type, blood pressure and cardiac function immediately after surgery and the others were extracted.

Inclusion and exclusion criteria: patients with TOF underwent pulmonary valve replacement with and without cardiac arrest and under the tetralogy of Fallot total correction (TFTC) procedure in past history. Subjects with, chronic heart disease, diabetes and chronic renal failure not be included in this study.

Operative approach

After induction of general anesthesia, under direct vision sternotomy incision was performed using oscillating saw. Cautiously all adhesions were. In on-pump with cardioplegic arrest procedures standard bicaval or in some cases single right atrial to aorta cannulation was established and on occasion, arteriovenous femoral cannulation as necessary. thermic CPB was then established and the operation was accomplished using arrested-heart technique [2].

In technique without cardiac arrest surgery (on pump beating heart) using a pump, but the heart is constantly beating and contraction dur-

Table 1. Distribution of surgery time (hours), cardiopulmonary pump time (minutes) and intubated time (hours) by surgical method

Variable		With cardiac arrest	Without cardiac arrest	Total
Surgical time (hours)	>2	0 (0/0%)	10 (3/30%)	10 (3/30%)
	3-2	7 (2/21%)	5 (2/15%)	12 (4/36%)
	4-3	3 (1/9%)	1 (0/3%)	4 (1/12%)
	5-4	5 (2/15%)	0 (0/0%)	5 (2/15%)
	>5	2 (0/6%)	0 (0/0%)	2 (0/6%)
P Value=045				
Pump time (minutes)	<30	1 (0/3%)	0 (0/0%)	1 (0/3%)
	60-31	9 (2/27%)	9 (2/27%)	18 (6/55%)
	>120	7 (2/21%)	7 (2/21%)	14 (4/42%)
P Value=021				
Intubated time (hours)	>3	0 (0/0%)	17 (6/51%)	17 (6/51%)
	6-3	1 (0/3%)	0 (0/0%)	1 (0/3%)
	9-6	5 (2/15%)	0 (0/0%)	5 (2/15%)
	12-9	3 (1/9%)	0 (0/0%)	3 (1/9%)
	15-12	2 (0/6%)	0 (0/0%)	2 (0/6%)
	18-15	4 (1/12%)	0 (0/0%)	4 (1/12%)
	<18	1 (0/3%)	0 (0/0%)	1 (0/3%)
P Value=033				

ing the operation, and its electrical and mechanical activity is not stopped. This procedure is performed using ascending aortic cannulation and a two-stage cannula, which is inserted into the right atrium [9], and if necessary, femoral vein was used. In this method, it is not the aortic clamping and cardioplegic is not given and the cardiac function does not stop. Therefore, the main difference between the two methods is aortic cross clamping and give the cardioplegic and without aortic cross clamping and no cardioplegia so without cardiac arrest. All together, in the first method, the heart will be arrested and in the second method the heart will be beating.

Patient follow-up

All patients were placed postoperatively on antiplatelet therapy with aspirin (and warfarin). Scheduled follow-up included clinical assessment, electrocardiography and transthoracic echocardiography taken at one-month intervals. Clinical assessment including exercise capacity and detection of symptoms and signs of right heart failure. ECG study and MRI was reserved for those patients with sign of RV malfunction. We recorded renal failure; intensive care unit and hospital stay; use of an inotropic agent; cardiac hemodynamic changes; infections and bleeding.

Statistical analysis

Statistical analysis of all data will be performed using the SPSS program, version 16.0 (SPSS Inc., Chicago, IL). Preoperative and postoperative variables were compared by independent t test, U Mann-Whitney, chi-square test and Fisher's exact test. The probability of $P<0.05$ was considered to show significant differences for all comparisons made. All results were expressed as mean ± standard deviation or number and percent.

Results

The mean age of the patients with cardiac arrest was 8/81 ± 7 years compared with 8.47 ± 8.37 years in without cardiac arrest. The lowest and highest age of the patients were 1 and 29 years, respectively (data not shown).

As shown in **Table 1**, the shortest surgical time was 90 minutes in without cardiac arrest and the longest surgical time of 390 minutes was recorded in the with cardiac arrest group. The mean surgical time in without and with cardiac arrest group 139.7 ± 37.44 and 234.7 ± 72, respectively. There was a statistically significant difference between the two groups regarding the duration of surgery ($P<0.05$). Patients without cardiac arrest had less surgical duration. The mean time of use of the cardiopulmonary pump in the group was 64.4 ± 22.7 and in the group without arrest, and 58.1 ± 20.1 in subject with cardiac arrest, and 61 ± 21 minutes in total. The lowest pump time was recorded for 30 minutes in the group without cardiac arrest and the highest in the arteries group was 120 (**Table 1**). As it can be seen, this variable was almost the same in the two groups and there was no significant difference between the two groups ($P>0.05$). Also, in patent without cardiac arrest, the amount of bleeding in the 24 hours after surgery was 634.4 ± 792.99 cc, and in subject with cardiac arrest group, none

Table 2. ICU and hospital stay (days) in the two groups

Length of stay in ICU	With cardiac arrest	Without cardiac arrest	*P* value
1	0	12	(P=0.025)
2	52	5	
3-6	14	1	
7-13	13	12	
>13	2	3	

of the 17 cases not bleeding within 24 hours after surgery (P=0.001).

As shown in **Table 2**, on median ICU stay 2/6 ± 0.90 days in two groups. While 70.6% of the patients without arrest were admitted to the ICU only one day, 87.5% of the patients with arrest were admitted for more than 2 days in ICU. There was an important difference between the groups in terms of intensive care unit and hospital stay; the hospital stays of patients in with and without cardiac arrest was 11.3 ± 4.1 and 10 ± 3.7, respectively. These were significantly shorter in without cardiac arrest group than with cardiac arrest group (P=0.025 and P=0.01, respectively).

By transthoracic echocardiography, post-surgery left ventricular ejection fraction was 48% ± 9% in patients with cardiac arrest and 55.8% ± 18% in without cardiac arrest. There was a significant difference in the EF before and after surgery in the surgical without arrest group (P=0.08). There was no significant difference in patent with arrest (P>0.05). Also, the difference between the two groups after surgery was statistically significant (P=021). for more information, see **Figure 1**.

Discussion

After pulmonary valve replacement, PVR with low ejection fraction has been associated with poor prognosis and may increase morbidity and mortality. Despite new myocardial protection techniques, postoperative adverse events related to myocardial reperfusion have not been completely eliminated. Indeed, the ideal solution to this problem use alternative technique, such as an off-pump beating-heart technique or an on-pump beating-heart technique with CPB. This study has shown that an on-pump beating-heart without cardiac arrest technique provides a significantly lower hospital and ICU stay, amount of bleeding and the need for postoperative inotropic support than conventional cardiac arrested. In addition, our study has shown that, patients undergoing pulmonary valve replacement without cardiac arrest had a better cardiac output compared with those operated with cardiac arrest.

Several years after surgery and correction of TOF, these patients experiencing a severe pulmonary regurgitation that need to be replaced [23]. The serious effects of PR are now widely recognized. PVR was mostly considered for symptomatic patients with PR [6]. The classic method of open heart surgery with CPB, along with some benefits, have side effects such as; ischemic reperfusion, myocardial infarction [3], dysrhythmia, and bleeding. Even though the adverse events related to CPB itself cannot be avoided, the avoidance of cardiac arrest makes the beating heart technique a rational alternative for patients with poor prognosis [24, 25].

Studies have suggested that on-pump without arrest heart surgery can reduce cardiac and systematic complications. In addition, in some situations, such as elderly patients and renal failure, pulmonary disease and severe constriction of the descending aorta have not good outcome with CPB, are made possible through beating-heart without cardiac arrest technique [26, 27]. Previous studies have controversial results [28-30]. In our study, the need for inotropic support, blood transfusion requirements, and intubation times lower than cardiac arrested technique.

Myocardial reperfusion syndrome occurs during cardiac arrest which prevented by surgery without cardioplegic [31]. As it shown in our study, we did not detect any patients with low cardiac output (LOC) syndrome post-surgery. also in previous studies, clinical improvement has been reported after pulmonary valve replacement. Although, the ideal time for this surgery is not to be found yet [32].

There is evidence that on-pump pulmonary valve replacement with and without cardioplegic arrest may not be as well protected from ischemia as on-pump procedure. As previous study shown that cardiac enzymes levels were higher with on-pump than off-pump techniques

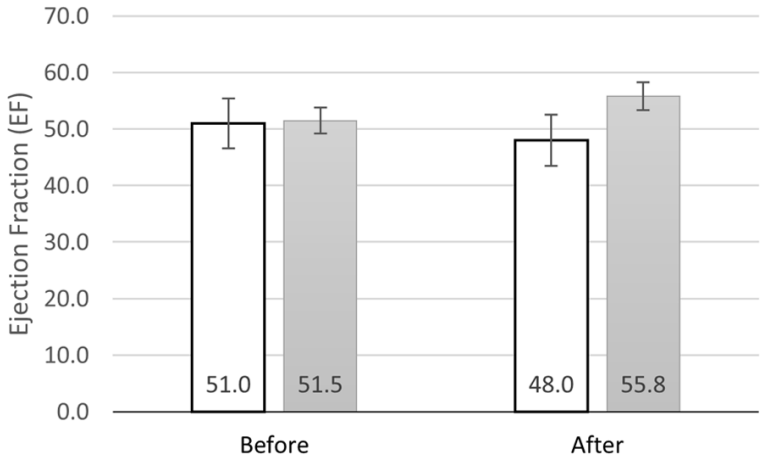

Figure 1. Comparison of Ejection Fraction (16) before and after surgery in both group.

[33]. Nevertheless, patients with ventricular dysfunction may be unable to tolerate a cardiac output during the off-pump techniques; therefore, the theoretical in this cases need exists for mechanical support from an on-pump procedure. in our study It has been demonstrated that a without cardioplegic arrest technique reduces myocardial injury compared with cardioplegic arrest, and this result is consistent with those reported in several studies [34, 35].

Advantages and disadvantages of without cardioplegic arrest surgery are as follows: Advantages: rapid recovery, decrease complications of CPB, reduced hospital and ICU stay, reduced mortality, faster return to normal daily activities, avoiding the manipulation of the aorta, low mortality rates in patients with left ventricular dysfunction and cardiogenic shock [36, 37]. Disadvantages; hard-to-reach different areas of the heart, lack of blood supply during surgery, increased risk of bleeding, direct damage to anatomical structure and lack of adequate information in this area [18, 38]. However, in our study, none of these complications was observed.

Several limitations exist concerning the present study. First our data are limited by the retrospective design. Secondly, the present study focuses only on the early patient outcomes.

In conclusion, current evidence from retrospective studies between PVR subject with and without cardiac arrest indicates that at short-term follow-up, all patients without cardiac arrest technique are alive and asymptomatic, with no signs of bleeding or infection and better cardiac output. Bigger sample size, longer follow-up, more assessment, and carrying out a controlled randomized trials are required to clearly determine the efficacy of the pulmonary valve replacement without cardiac arrest compared the surgery with cardiac arrest. The surgery without cardiac arrest could be an alternative for high-risk patient instead of on-pump procedure.

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Disclosure of conflict of interest

None.

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