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Research Article

Incidence, Predisposing Factors and Prognosis of Acute Postoperative Rv Failure in Cardiac Surgery: A Prospective Cohort Study

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Abstract

Objective: To study the incidence, risk factors and outcome of acute right ventricular failure (RVF) in cardiac surgery under extra-corporeal circulation (ECC) patients.

Design: A prospective cohort study over one year. Were included, patients candidates for cardiac surgery (CS) with ECC and having a normal RF systolic function. Transthoracic-echocardiography (TTE) Doppler was performed on day 1, day 3, day 7 and 1 postoperative month. TAPSE < 13 mm and an S-wave velocity < 10 cm/s during the first postoperative week defined the postoperative-CS-RVF (POCS-RVF). Thus, patients were divided into two groups (POCS-RVF group versus non POCS-RVF group) and compared. Outcomes were: catecholamine support, septic events, length of stay (LOS), ventilator days and 30-day mortality.

Results: 128 among 131 patients were included (POCS-RVF group, n = 49 versus non POCS-RVF, n = 79). The incidence of acute POCS-RVF was 38.2%. Acute RVF occurred at the 1st post-operative day and remained during 7 days. Mitral valve replacement, aortic clamping time above than 90 minutes, preoperative arrhythmia and bleeding were significantly related to acute POCS-RVF with respectively (OR = 11.75; IC [2.18 - 13.16]), (OR = 4.36; IC [1.01 - 18.68]), (OR = 6.55; IC [2.38 - 17.96]), (OR = 3.4; IC [2.38 - 17.96]). Acute POCS-RVF increased mortality [21 (43%) vs 16 (20%), p = 0.006] and reduced survival time by 5 days but no significant link was showed between POCS-RVF and death. It depended to the left ventricular (LV) systolic function. LV dysfunction in POCS-RVF patients increased the death risk by 3 and its absence improved survival. Other factors were significantly associated to mortality Bentall and coronary tube procedures and ECC time > 120 minutes.

Conclusion: We conclude to a high incidence of acute POCS-RVF. Several preoperative factors predispose to this phenomenon. LV failure worsened the outcome. These findings should sustain preventive measures to limit myocardial damage during cardiac surgery.

Keywords: *Cardiac Surgery; Extracorporeal Circulation; Right Ventricular Failure; Transthoracic Echocardiography-Doppler; Left Ventricular; Incidence; Risk Factors; Outcome*

Abbreviations

RV: Right Ventricle; LV: Left Ventricular; CS: Cardiac Surgery; POCS: Postoperative Cardiac Surgery; RVF: Right Ventricular Failure; TTE: Transthoracic-echocardiography; ECC: Extracorporeal Circulation; TAPSE: Tricuspid Annular Plane Systolic Excursion; MT: Motion Time; DTI: Doppler Tissue Imaging; ASE: American Society of Echocardiography; EACVI: European Association of Cardiovascular Imaging; LVEF: LV Ejection Fraction; MRI: Magnetic Resonance Imaging; ECMO: Extra-corporeal Membrane Oxygenation; IABP: Intra-Aortic Balloon Pump; ICU: Intensive Care Unit; SPAP: Systolic Pulmonary Arterial Pressure; LOS: Length of Stay; BMI: Body Mass Index; MVR: Mitral Valve Replacement; AVR: Aortic Valve Replacement; CAB: Coronary Artery Bypass; SV: Supra Ventricular; OR: Odds Ratio; CI: Confidence Interval

Introduction

For a long time, the right ventricle (RV)'s role in the global cardiac function was neglected and even called the "forgotten chamber" [1,2]. But currently, it is recognized that the cardiac system runs in series and that the left ventricular (LV) systolic ejection depends on the

preload provided by the RV. The RV failure occurs when the RV fails to maintain enough blood flow through the pulmonary circulation to achieve adequate left ventricular filling [3]. Trans-thoracic ultrasound is a simple and reproducible tool for studying RV systolic function via the right ventricular longitudinal contraction parameters. The most common recommended indices are: the Tricuspid Annular Plane Systolic Excursion (TAPSE) measured in motion time (MT) mode and the velocity of the S wave measured by Doppler Tissue Imaging (DTI), both focused on the lateral side of the tricuspid ring in 4-cavities incidence. According to the American Society of Echocardiography (ASE) and the European Association of Cardiovascular Imaging (EACVI) [4], a TAPSE value of less than 17 mm and a velocity of the S wave of less than 10 cm/s defined RV's contractile dysfunction. These parameters are well correlated with the RV ejection fraction (RVEF) measured in magnetic resonance imaging (MRI); considered as the gold standard technique [5,6].

In cardiac surgery requiring extracorporeal circulation (ECC), the RV failure is a topic of an increasing interest; mainly its prognostic value. Severe postoperative -cardiac surgery - RV failure (POCS-RVF), particularly with cardio-circulatory assistance such Extra-corporeal membrane oxygenation (ECMO) or intra-aortic balloon pump (IABP) occurred with an incidence ranging from 0.04 to 0.1% [7]. Despite of therapeutic progress in the per-operative management, the POCS-RVF is related to a significant mortality (25 to 30%) [7]. It should be noted nonetheless, that it is difficult to attribute the hemodynamic insufficiency in POCS, only to the RVF given the strong interaction RV/LV.

Aim of the Study

Herein, we aimed to study the incidence, risk factors and outcome of POCS-RVF by comparing two groups of patients who presented versus not a RVF following cardiac surgery with ECC.

Methods

Study design

Prospective, observational with analytical approach study conducted in the Cardiovascular Surgery Department of La Rabta Hospital, over one year period (December 2016 - December 2017). The study was in accordance with the ethical standards of declaration of Helsinki and approved by the local ethics committee of la Rabta hospital. Given the non-interventional nature of the protocol study, informed consent was not required. All patients were informed by participation in the study.

Study population

Study population were enrolled prospectively, all patients admitted during the study period older than 18 years and candidates for cardiac surgery (CS). Among them, were included those with normal RF systolic function in the echocardiography-assessment before CS.

Non-inclusion criteria were: presence before CS of RV failure or LV systolic dysfunction, history of pulmonary embolism, chronic respiratory failure, cardiac surgery, arrhythmia and tricuspid valve surgery. The occurrence of anaesthesia-related complication was an exclusion criterion.

Study protocol, echocardiography details and definitions

Immediate postoperative patients were admitted to the post-op cardiac surgery intensive care unit (ICU). Transthoracic-echocardiography (TTE) Doppler was performed by a professor in cardiac surgery and former echocardiography practitioner on day 1, day 3, day 7 and 1 postoperative month. The used ultrasound device was General Electric brand ultrasound system (Vivid S5). TAPSE and S-wave were measured in 4 cavities incidence using respectively the motion time (TM) mode and tissue Doppler mode both focused on the lateral side of tricuspid annular; according to the ASE and the EACVI guidelines [4]. TAPSE < 13 mm and an S-wave velocity < 10 cm/s during the first postoperative week defined the POCS-RVF and distinguished two groups (POCS-RVF group versus non POCS-RVF group). a LVEF ≤ 40% defined the LV systolic dysfunction.

Data collection and outcomes

Demographic (age, sex, ASA class) and anthropometric parameters were collected, as well as the cardiac surgery details: type of surgery, duration of EEC, duration of aortic clamping, requiring of circulatory assistance such ECMO or IABP and preoperative cardiac complications (arrhythmia, conduction disorders, haemorrhagic accident, blood transfusion...). We recorded the follow up of echocardiography parameters [TAPSE, S-wave velocity, systolic pulmonary arterial pressure (SPAP) and LVEF] and troponin dosage at day 1, 3, 7 and 30 after CS. Outcomes were: catecholamine support, septic events, ICU length of stay (LOS), ventilator days and 30-day mortality.

Statistical analysis

Data entry and processing was performed with IBM SPSS STATISTICS software (version 20). Qualitative variables were expressed as percentages and quantitative variables as means ± standard deviation (SD) or median [inter quartile range (IQR) 25 - 75 percentile] as appropriate. Quantitative variables were compared using Student T or Mann-Whitney test as appropriate. Pearson and Fisher chi-square tests were used for comparing qualitative variables. Logistic regression was used twice times: firstly, for analysing the association between risk factors/ POCS-RVF and secondly, for analysing the association between POCS-RVF/mortality. It included all covariates with $p < 0.2$ in the univariate model. The Kaplan-Meier method was used for survival analysis. Statistical analysis was carried out using two sided tests and significance level was fixed at 0.05.

Results

Patient's flow and incidence of POCS-RVF

During the study period, 128 among 131 patients were included. Three patients were excluded for occurrence of cardiac arrest during extracorporeal circulation. The ultrasound follow-up diagnosed the postoperative - cardiac surgery - RV failure (POCS-RVF) in 49 patients. The annual incidence of POCS-RVF was 38.2% and our study population was divided into 2 groups (POCS-RVF group, n = 49 versus non POCS-RVF, n = 79).

Patient's baseline characteristics

Almost all patients have an overweight (body mass index: BMI > 25), but the mean BMI of the POCS-RVF group was significantly higher. Regarding the demographic criteria, anaesthetic scores and co morbidities, both groups were similar. Likewise, preoperative echographic (LVEF, TAPSE, S-wave velocity and SPAP) parameters did not differ between the 2 groups (Table 1).

	POCS-RVF group (n = 49)	Non POCS-RVF (n = 79)	p value
Age, years (mean ± SD)	57,1 ± 16,39	56,31 ± 12,75	0,76
Sex ratio (M/F)	2.26	1.82	0.57
BMI, Kg/m^2 (mean ± SD)	29,24 ± 6.14	26,96 ± 6.03	0,04
Euroscore II, (%) (mean ± SD)	1.3 ± 0.5	1.22 ± 0.8	0.06
ASA II, n (%) ASA III, n (%)	29 (59) 20 (41)	47 (59) 32 (41)	0,97 1
NYHA I, n (%) NYHA II, n (%) NYHA III, n (%)	9 (18) 35 (71) 5 (10)	17 (22) 59 (75) 3 (4)	0,33 0.8 0.12
Co morbidities, n (%): Tobacco Hypertension Diabetes Coronary disease CPAD Ischemic *stroke* Dyslipidemia	 34 (69) 22 (45) 25 (51) 17 (35) 5 (10) 7 (14) 24 (49)	 52 (66) 46 (58) 37 (47) 32 (41) 7 (9) 11(14) 32 (40)	 0,67 0,14 0,64 0,37 0,8 0,95 0.34
Echo graphic parameters: LVEF, % (mean ± SD) TAPSE, mm (mean ± SD) S-DTI, cm/s (mean ± SD) SPAP, mm Hg (mean ± SD)	 53 ± 5,1 21 ± 1,6 11,59 ± 0,95 29 ± 3,15	 55 ± 7.12 22 ± 1,5 11,88 ± 0,87 28,8 ± 3,38	 0.13 0.15 0.07 0.42

Table 1: *Patient's baseline characteristics.*

POCS: Postoperative Cardiac Surgery; RVF: Right Ventricular Failure; SD: Standard Deviation; BMI: Body Mass Index; ASA: American Society of Anaesthesiologists; NYHA: New York Heart Association; CPAD: Chronic Peripheral Artery Disease; LVEF: Left Ventricular Ejection Fraction; TAPSE: Tricuspid Annular Plane Systolic Excursion; S: S Wave Velocity; DTI: Doppler Tissue Imaging; SPAP: Systolic Pulmonary Arterial Pressure.

Surgical data

The major reason for cardiac surgery, in all patients, was coronary disease. Otherwise, mitral valve diseases and aortic valve diseases were the most indications respectively in POCS-RVF and non POCS-RVF groups. Therefore, mitral valve replacement was the major surgery in the RVF group while aortic valve replacement in the non-RVF group. For the preoperative events, the durations of EEC and aortic

clamping were significantly longer for the POCS-RVF group. Similarly, rhythm disorder and bleeding with transfusion requirements were more frequent with this group (Table 2).

	POCS-RVF group (n = 49)	Non POCS-RVF (n = 79)	p value
Indications for CS:			
Aortic valve stenosis, n (%)	1 (2)	16 (20)	0.003
Mitral valve stenosis, n (%)	10 (20)	6 (8)	0.007
Aortic insufficiency, n (%)	3 (6)	13 (16)	0.086
Mitral insufficiency, n (%)	11 (22)	12 (15)	0.03
Coronary diseases, n (%)	12 (24)	29 (37)	0.15
Aortic dissection type A, n (%)	5 (10)	3 (4)	0.14
Ascending aortic aneurysm, n (%)	2 (4)	8 (10)	0.21
Mitral and aortic valvular disease, n (%)	5 (10)	6 (8)	0.6
Surgical intervention's nature, n (%):			
MVR	41%	11%	< 0.001
AVR	8%	27%	0.01
CAB	25%	37%	0.15
Double replacement	10%	9%	0.8
Bentall procedure	10%	4%	0.14
Coronary addition tube	4%	10%	0.21
MV repair	2%	3%	0.85
Per-operative events:			
ECC time, min (mean ± SD)	121,7 ± 10	111,5 ± 13	< 0.001
Aortic clamping time, min (mean ± SD)	96 ± 9	85 ± 10	< 0.001
Supraventricular rhythm disorders, n (%)	36 (73)	21 (26)	< 0.001
External electric shock, n (%)	36 (3)	21(26)	< 0.001
Conduct disorder, n (%)	19 (39)	36 (46)	0.45
Pacemaker dependancy, n (%)	19 (39)	32 (40)	0.84
Bleeding, n (%)	26 (53)	17 (22)	< 0.001
Transfused RCC, number (mean ± SD)	3.6 ± 1.11	1.7 ± 0.8	< 0.001
Transfused FFP, number (mean ± SD)	4.6 ± 2.2	2.6 ± 1.2	0.001
Transfused PC, number (mean ± SD)	8.2 ± 4.7	4.05 ± 2	0.004

Table 2: *Surgical data in study groups.*

CS: Cardiac Surgery; POCS: Postoperative Cardiac Surgery; RVF: Right Ventricular Failure; MVR: Mitral Valve Replacement; AVR: Aortic Valve Replacement; CAB: Coronary Artery Bypass; EEC: Extracorporeal Circulation; SD: Standard Deviation; RCC: Red Cell Concentrates; FFP: Fresh Frozen Plasma; PC: Platelet Concentrates.

Post-operative cardiac assessment

Ultrasound parameters measured on days 1, 3, 7 and 30 postoperative are displayed in figure 1. There was a decrease in the LVEF from day 1 after CS, both in the two groups, but it was lower in the POCS-RVF group. In addition to the decrease of TAPSE and S-wave velocity in TDI during the assessment period, SPAP was higher in the POCS-RVF group in all measurements. In the POCS-RVF group, the improvement of TAPSE and S-wave velocity was observed from day 7 (Figure 2). The biologic monitoring of troponin did not differ between the 2 groups in day 1, 3 and 7 after cardiac surgery.

Factors associated to PO-CS-RVF

Among the selected variables in the univariate analysis: MVR, aortic clamping time> 90 min, occurrence of bleeding and rhythm disorders were significantly related to the postoperative RVF. The factor: BMI > 25 Kg/m^2 was close to significance (Table 3).

Outcomes and relation to mortality

The PO-CS-RVF group required more inotropic support (3.4 ± 2 vs 2.3 ± 1.8 days, p = 0.002), prolonger cardiac ICU-LOS (4.97 ± 2.2 vs 4.07 ± 1.74, p = 0.01) and higher mortality [21 (43%) vs 16 (20%), p = 0.006]. The requirement of ECMO or IABP, ventilator days, infectious complications and the surgical revision rate were comparable between the 2 groups.

The PO-CS-RVF was not an independent factor related to mortality (OR = 2,65; CI [0,32 - 21,66]) and it depended significantly to the LVF (LVEF < 40%). A stratified analysis on this last factor showed that in presence of POCS-RVF, a LVEF < 40% increased the risk of death by 3 (OR = 3.96, 95% CI [1.5 - 10.4]) and. On the other hand, a LVEF > 40% was a survival factor (OR = 0.75, 95% CI [0.61 - 0.93]). In addition, the Bentall procedure, coronary tube and ECC time> 120 min were independent of excess mortality with respective ORs at OR = 16; CI [1.53 - 267], OR = 86; CI [5,44 - 137] and OR = 9,36; CI [1.78 - 49].

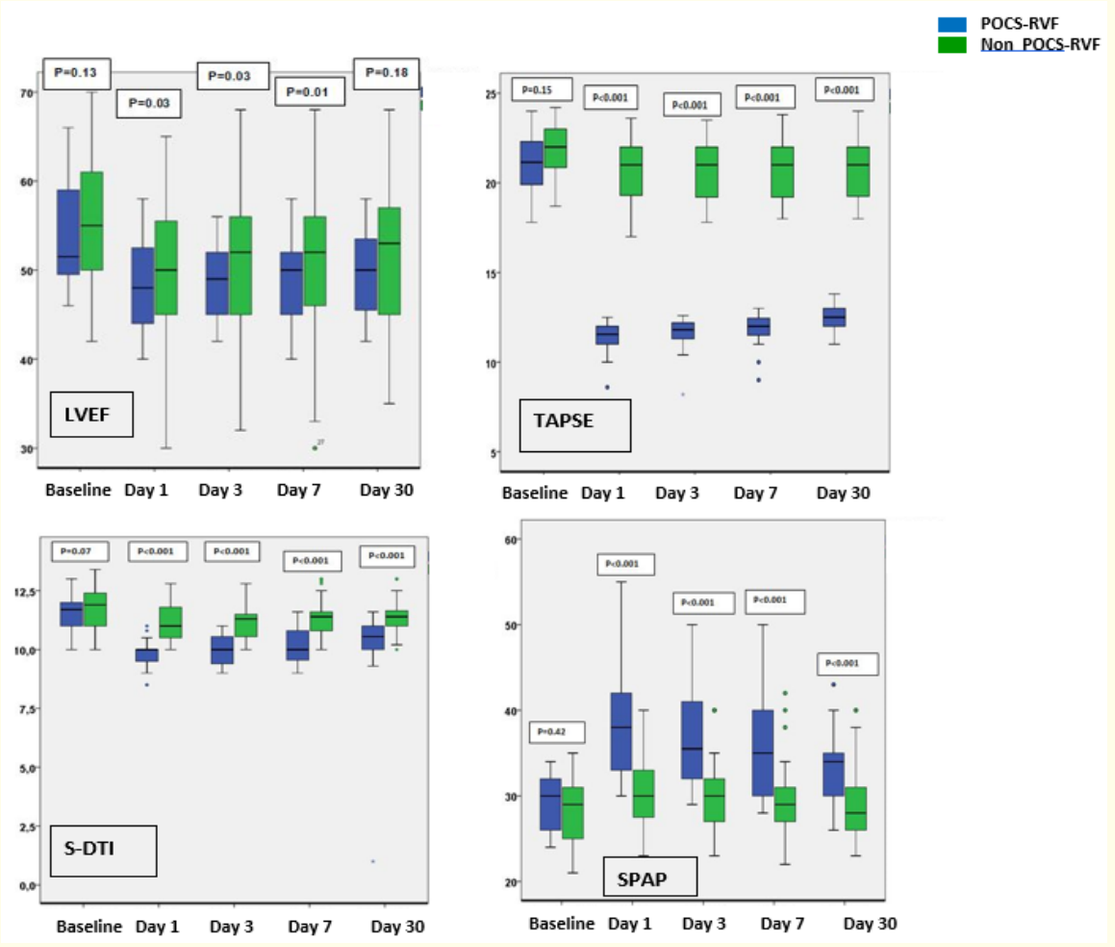

Figure 1: *Post-operative cardiac ultrasound assessment.*

POCS: Postoperative Cardiac Surgery; RVF: Right Ventricular Failure; LVEF: Left Ventricular Ejection Fraction; TAPSE: Tricuspid Annular Plane Systolic Excursion; S: S Wave Velocity; DTI: Doppler Tissue Imaging; SPAP: Systolic Pulmonary Arterial Pressure.

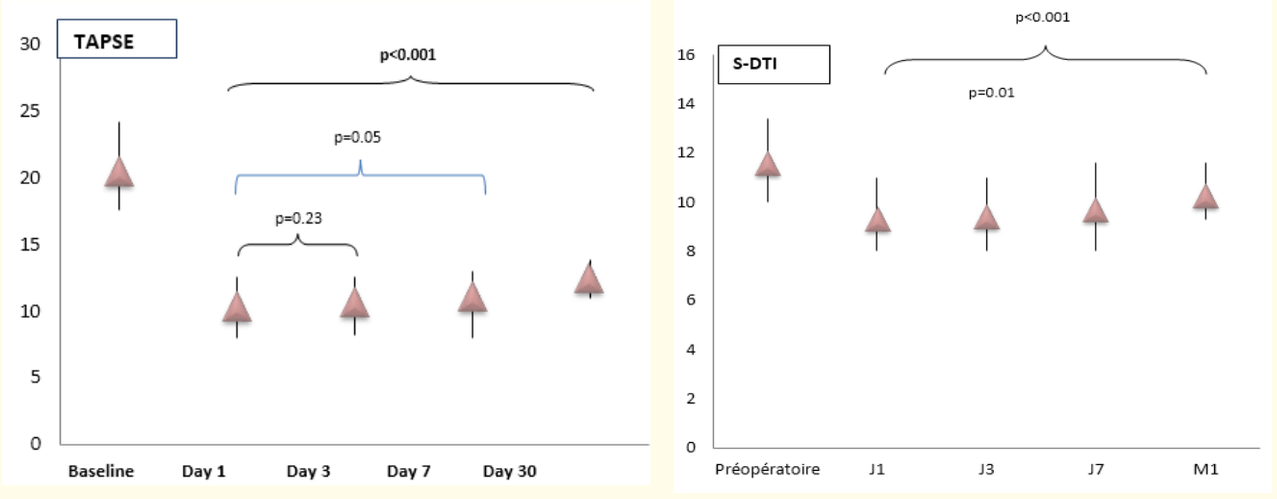

Figure 2: *Postoperative evolution of TAPSE (mm) and S wave velocity (cm/sec) in POCS-RVF group.*

POCS: Postoperative Cardiac Surgery; RVF: Right Ventricular Failure; TAPSE: Tricuspid Annular Plane Systolic Excursion; S: S Wave Velocity; DTI: Doppler Tissue Imaging.

	Univariate analysis OR [95% CI]	Multivariate analysis OR [95% CI]
Patient factors		
Age > 55 years	1.06 [0.51 - 2.17]	
BMI > 25 Kg/m^2	2.7 [1.24 - 5.84]	2.83 [0.99 - 8.09]
Hypertension	0.58 [0.28 - 1.2]	
Diabetes	1.18 [0.57 - 2.41]	
Coronary disease	0.85 [0.4 - 1.77]	
CS Factors		
MVR	5.36 [2.18 - 13.16]	11.75 [2.18 - 13.1]
AVR	0.24 [0.07 - 0.76]	
Double VR	1.16 [0.34 - 3.9]	
CAB	0.55 [0.25 - 1.23]	
Bentall procedure	2.87 [0.65 - 12.63]	
Coronary addition tube	0.37 [0.07 - 1.85]	
MV repair	0.8 [0.07 - 9.08]	
ECC time >120 min	3.18 [1 - 6.71]	1.07 [0.24 - 4.6]
Aortic clamping time > 90 min	4.72 [2.19 - 10.16]	4.36 [1.01 - 18.6]
SV rhythm disorders	7.64 [3.41 - 17.14]	6.55 [2.38 - 17.9]
Bleeding	4.12 [1.89 - 8.96]	3.4 [1.17 - 9.8]

Table 3: *Factors associated to PO-CS-RVF: results of univariate and multivariate analysis's.*

CS: Cardiac Surgery; POCS: Postoperative Cardiac Surgery; RVF: Right Ventricular Failure; BMI: Body Mass Index; MVR: Mitral Valve Replacement; AVR: Aortic Valve Replacement; CAB: Coronary Artery Bypass; EEC: Extracorporeal Circulation; SD: Standard Deviation; SV: Supra Ventricular; OR: Odds Ratio; CI: Confidence Interval.

Survival was better in the non POCS-RVF group comparatively to the other group and the survival delay was shortened by an average of 5 days in patients with RVF (Figure 3).

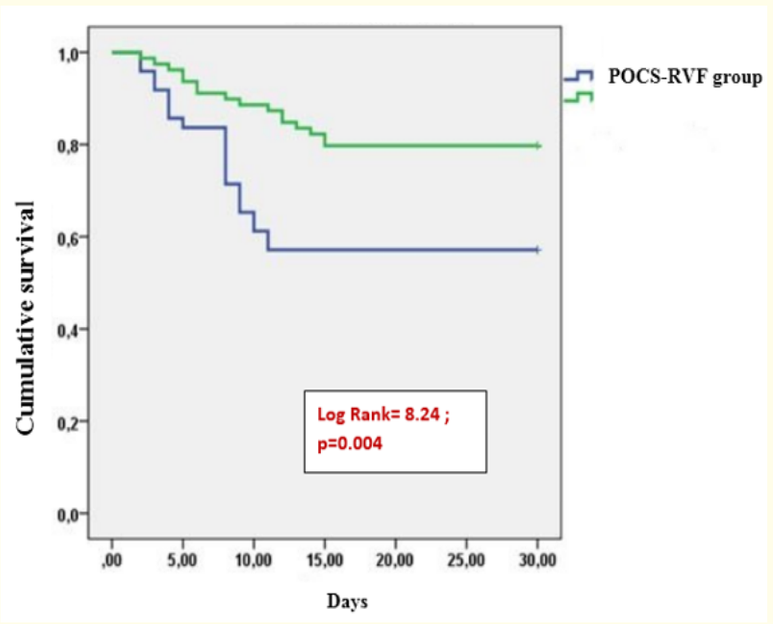

Figure 3: *Survival analysis.*

POCS: Postoperative Cardiac Surgery; RVF: Right Ventricular Failure.

Discussion

We showed that more than a third of cardiac surgery patients presented a RV failure (38.2%). The RVF, diagnosed by Doppler-TTE with measurement of TAPSE and S-wave velocity, was observed from day 1 after CS which persisted until day 7. MVR, aortic clamping time above than 90 minutes, SV arrhythmia and per-operative bleeding were significantly related to the occurrence of POCS-RVF. This complication increased mortality and reduced survival time by 5 days on average but no significant link was showed between POCS-RVF and death. The LVF influenced the prognosis of patients with POCS-RVF. Its presence increased the death risk by 3 and its absence improved survival. Other factors were significantly associated to mortality such Bentall and coronary tube procedures and ECC time > 120 minutes.

Epidemiologic data

Our post cardiac surgery-RVF's incidence was higher than literature data that reported an incidence between 2 and 6% [8]. Others reported even a lower incidence of 0.04 and 0.01% due to the improvement in techniques and tools of cardio protection [7,9]. This difference is explained by the type of RVF that was studied. The studies mentioned above were focused on RVF refractory to any therapy and mainly to biventricular dysfunction requiring ECMO or mechanical support type RVAD (Right Ventricular Assist Device) [7].

Deterioration of RV function during cardiac surgery

From an etiopathogenic view, several hypotheses were suggested to explain the impairment of the RV function after cardiac surgery. Among these assumptions we hold, without much detail, geometric changes [10-15], ischemia-reperfusion phenomena and oxidative stress injury [16-21]. In addition, we showed that that the type of cardiac surgery and mainly the MV replacement, was a determining factor in the impairment of RV function. Few data have investigated the impact of valvular surgeries on the RV function. Reynolds., et al. [21] showed that mitral surgery caused the appearance of a paradoxical septal movement. Günday., et al. [22] reported that the occurrence of paradoxical septal movement was associated more in surgery under cardiopulmonary bypass compared with closed cardiac surgery.

The preoperative SV arrhythmia was also associated to the RVF in our series. This result was not found previously. Deterioration of RV function during arrhythmia is explained basically; by the LV/RV interdependence, since LV filling is affected by the absence of atrial systole involvement. Outside cardiac surgery, in the series of Alam., *et al.* [23], the median TAPSE in patients with arrhythmia was significantly lower than that of a control group in sinus rhythm, (13 ± 4 vs 25 ± 4 mm) with improvement after cardio version.

In addition, in our study, per operative bleeding was related to RVF after CS. Its impact on the deterioration of RV function was reported by Itagaki., *et al* [24]. Bleeding affects the blood volume which is yet reduced per ECC. This influences the biventricular function and partly explains the reduction of LVEF that we noted postoperatively.

Assessment of systolic RV function in cardiac surgery patients

The RV systolic function was assessed by the ultrasound tool with measurement of the TAPSE and S-wave velocity. These two indices represent a simple and reproducible method. Kaul., *et al.* [25] showed a good correlation with the RVEF measured by radioisotopic angiography ($r = 0.92$, $p < 0.001$). The TAPSE was also validated compared to the RVEF measured in MRI [5] ($r = 0.86$, $p < 0.0001$) and in conditions of ischemia [6] ($r = -0.63$, $p < 0.0001$). S-wave velocity is correlated with isotopic RVEF [26] ($r = 0.65$, $p < 0.001$) and showed good accuracy to define RV systolic failure. TAPSE and the S wave are therefore parameters of common practice to evaluate RV systolic function in healthy and critically patients [27]. New methods have emerged more recently to study the RV function The measurement of RVEF in 3D ultrasound is a feasible method in 85% of population (outside context of cardiac surgery) [28] and it is highly correlated with MRI-RVEF ($r = 0.97$) [29]. However, its use in daily practice is limited by the need for post-treatment software. Unlike TAPSE and S wave, strain technique measurement is independent of the angle of incidence. Chow and Leong showed a good correlation between the RV strain analysis and MRI-RVEF [30,31]. However, its use is not recommended in daily practice [4].

RVF after cardiac surgery and mortality

To the literature review, association between post CS-RVF and mortality varies widely. Reichert., et al. [10] showed a higher mortality in patients who developed a POCS biventricular dysfunction comparatively to the patients with only LV dysfunction. Denault., et al. [11] reported a mortality rate at 37% in the post CS RVF with pulmonary arterial hypertension. In our series, mortality in POCS-RVF group was considerable at 43% and reduced survival. Nevertheless, RVF-related mortality was dependent on the LV function. This further strengthens the results of Reichert., et al. [10] on the pejorative impact of interdependence LV/RV post cardiac surgery.

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Finally, we believe that it is compulsory to establish a management protocol in order to optimize the myocardial protection during cardiac surgery. The structural changes could be preventable by: promoting the Warm blood cardioplegia, limit the durations of ECC and aortic clamping, try as much as possible to preserve the geometrical cardiac structures, promoting the "beating-heart surgery", rapid management of blood loss but in the same time opt for a conservative transfusions strategy.

Conclusion

The acute postoperative Right Ventricular Failure is a not rare and early phenomenon in Cardiac Surgery. It is easy to diagnose by Doppler-TTE with measurement of TAPSE and S-wave velocity. Several preoperative factors predispose to this phenomenon. Once occurred, it worsens the prognosis particularly if the left ventricular failed. This should sustain some preventive measures to limit myocardial damage during cardiac surgery.

Declarations

Ethics Approval and Consent to Participate: Our study was performed in accordance with the Declaration of Helsinki and approved by the local ethics committee of la Rabta center. Given the non-interventional nature of the study protocol, informed consent was not required. Patients or their legal parents were informed by participation in the study.

Consent for Publication: Participants in this study approved their consent for publication of the data.

Availability of Data and Materials: All data generated or analyzed during the present study are included in this manuscript.

Competing Interests

The authors declare that they have no competing interests.

Funding

The authors declare that no funding was received.

Author's Contributions

AT drafted the manuscript; IBN performed the data collection, performed the statistical analysis and helped to drafting of the manuscript. AA, RD, MSM, SA and SBL provided clinical care and reviewed the manuscript with critical revision. All authors read and approved the final manuscript.

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