Comparative Study between CardiaMed and CarboMedics Medical Bileaflet Mechanical Heart Valve Prostheses in Aortic Position

Thesis

Submitted for Partial Fulfillment of MD Degree
in Cardiothoracic Surgery

By

Asser Mohamed Ahmed El Sakka
MB,B.CH., M.SC., General Surgery

Under Supervision of

Prof. Ahmed Baheig EL-Kerdany
Professor of Cardiothoracic Surgery
Faculty of Medicine, Ain-Shams University

Prof. Mostafa Abd EL-Azeem Abdel-Gawad
Professor of Cardiothoracic Surgery
Faculty of Medicine, Ain-Shams University

Prof. Hany Abd El-Maboud Metwaly
Professor of Cardiothoracic Surgery
Faculty of Medicine, Ain-Shams University

Dr. Hamdy Abd El-Wareth Sengab
Assistant Professor of Cardiothoracic Surgery
Faculty of Medicine, Ain-Shams University

Faculty of Medicine
Ain-Shams University
2016

سورة البقرة الآية: ٣٢

Acknowledgments

First and foremost, I feel always indebted to **Allah** the Most Beneficent and Merciful.

I am deeply grateful to **Prof. Ahmed Baheig EL-Kerdany,** Professor of Cardiothoracic Surgery, Faculty of Medicine, Ain-Shams University, for his unlimited help and giving me the privilege to work under his supervision. His care and support are really valuable and precious.

I would like also to express my deep appreciation and gratitude to **Prof. Mostafa Abd EL-Azeem Abdel-Gawad,** Professor of Cardiothoracic Surgery, Faculty of Medicine, Ain-Shams University, for his generous supervision, guidance and support throughout this work.

I can't forget to express my deep appreciation and gratitude to **Prof. Hany Abd El-Maboud Metwaly,** Professor of Cardiothoracic Surgery, Faculty of Medicine, Ain-Shams University, for his delicate

Last but not least, all thanks to **Dr. Hamdy Abd El-Wareth Sengab,** Assistant Professor of Cardiothoracic Surgery, Faculty of Medicine, Ain-Shams University, for the efforts and time he has devoted to accomplish this work.

Finally, I wish to extend my thanks to my **Mother** and the soul of my **Father** for pushing me forward in every step in the journey of my life.

Candidate

Asser Mohamed Ahmed El Sakka

Contents

List of Abbreviations

Abbr.	Full-term
ACC	Aortic cross clamp
AP septum	Aorticopulmonary septum
AR	Aortic regurge
AS	Aortic stenosis
AV	Aortic valve
AVA	Aortic valve area
AVR	Aortic valve replacement
BSA	Body surface area
CAD	Coronary artery disease
CO	Cardiac output
CPB	Cardiopulmonary bypass
EDD	End diastolic diameter
EF	Ejection fraction
ESD	End systolic diameter
HR	Heart rate
ICU	Intensive Care Unit
INR	International Normalized Ratio

LV	Left ventricle
LVEDP	Left ventricle end diastolic pressure
LVEDV	Left ventricle end diastolic volume
LVF	Left ventricle function
LVH	Left ventricle hypertrophy
LVOT	Left ventricle out tract
NYHA	New York Heart Association
PPG	Peak pressure gradient
SD	Standard deviation
SJM	St. Jude Medical (SJM) prosthesis
SPSS	Statistical package for social science
TA	Truncus arteriosus
VA junction	Ventriculoarterial junction

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Abstract

Background: Valve replacement still remains the mainstay surgical therapeutic option for patients with valvular heart disease. Unfortunately, to date, no prosthetic valve meets the criteria of the ideal valve that mimics a normal native valve and each of the currently available prosthetic valves has inherent limitations. Both CardiaMed valve and CarboMedics valve are bileaflet mechanical valve prosthesis of different designs. The CarboMedics valve is one of the most frequently implanted mechanical heart valve prosthesis worldwide. It has an extremely durable design with excellent hemodynamic function. The CardiaMed valve has multiple design features that is claimed to promote effective hemodynamics.

Aim of the Work: This study aims to compare the early postoperative hemodynamic function and major clinical events in patients receiving CarboMedics valve & CardiaMed valve in Aortic position.

Patients and Methods: this study included sixty patients of aortic valve disease patients who were scheduled for elective AVR at Ain Shams University Hospitals. These patients were randomly assigned into 2 groups: Group A**:** 30 patients received CarboMedics bileaflet mechanical valve; Group B**:** 30 patients received CardiaMed bileaflet mechanical valve. Study variables included:postoperative complications and valve function assessments with echocardiography.

Results: the postoperative complications in group A were: 1 patient re-explored for bleeding (3.3%), 1 patient had Rhythm disturbance and 2 cases of Wound infection, while in groupB: 1 patient re-explorated for bleeding, 2 patients had rhythm disturbance, 1 patient had wound infection, 1 patient had bleeding event, Regarding valve function all valves were working properly with no cases of valve obstruction or leaflet limitation or paravalvular leak or valve thrombosis.

Conclusion: the CardiaMed is an effective mechanical heart valve and has a comparable results with CarboMedics prothestic aortic valve.

Key word: Aortic valve prosthesis, CarboMedics, CardiaMed

Introduction

The introduction of valve replacement surgery in the early 1960s has dramatically improved the outcome of patients with valvular heart disease [(1)].

Approximately 90 000 valve substitutes are now implanted in the United States and 280 000 worldwide each year; approximately half are mechanical valves and half are bioprosthetic valves [(1)].

Despite the marked improvements in prosthetic valve design and surgical procedures over the past decades, valve replacement does not provide a definitive cure to the patient. Instead, native valve disease is traded for "prosthetic valve disease," and the outcome of patients undergoing valve replacement is affected by prosthetic valve hemodynamics, durability, and thrombogenicity [(1)].

Nonetheless, many of the prosthesis-related complications can be prevented or their impact minimized through optimal prosthesis selection in the individual patient and careful medical management and follow-up after implantation [(1)].

The ideal valve substitute should mimic the characteristics of a normal native valve. In particular, it should have excellent hemodynamics, long durability, high thromboresistance, and excellent implantability [(1)].

Unfortunately, this ideal valve substitute does not exist, and each of the currently available prosthetic valves has inherent limitations [(1)].

The ideal prosthetic heart valve should possess qualities that include good hemodynamic performance and durability, ease of insertion, and freedom from thromboembolic events. Although valve manufacturers aim for these objectives, no prosthetic valve has yet achieved a perfect performance profile in accordance with these criteria [(2)].

There are several design features that distinguish the CardiaMed valve from the CarboMedics valve [(2)].

The CardiaMed valve (CardiaMed; Penza, Russia) was first approved for clinical use in 2003. The valve contains 2 leaflets that rotate around a central axis. The leaflets are made of pyrolytic carbon, and the valve housing is reinforced with a stiff ring made of titanium alloy. The specially designed aerodynamic shape of the leaflets not only produces laminar flow but also accelerates valve opening and closure [(2)].

Based on the results of various studies, the CardiaMed heart valve displays an excellent hemodynamic profile and minimal rates of valve-related adverse events [(2)].

On the other hand, the CarboMedics bileaflet mechanical prosthesis was introduced in 1986 and until now more than 500,000 valves have been implanted [3].

The CarboMedics prosthesis has a solid pyrolite carbon housing and flat leaflets of pyrolite carbon coated graphite that is impregnated with tungsten [3].

The pyrolite carbon housing is reinforced by an outer stiffening ring composed of titanium which virtually eliminates the risk of leaflet escape. The design further enables valve rotation after implantation [3].

With the recommended international normalised ratio (INR) level for the CarboMedics aortic heart valve prosthesis the rate of embolic and bleeding events are low [3].

Thrombosis of a CarboMedics aortic valve prosthesis is rarely seen and is the result of inappropriate anticoagulation without pannus formation [3].

The incidence of prosthetic endocarditis is very low and this is also the case for noninfectious paravalvular leakage necessitating reoperation. Intrinsic dysfunction and/or structural failure has never been reported [3].