Recent Trends in Left Ventricular Assist Devices Implantation

An essay submitted for partial fulfillment of master degree in cardiothoracic surgery

Presented by

Hesham Mohamed Abdelhameed

M.B.B.Ch, Faculty of medicine- Al-Azhar University

Under supervision of

Professor / Gamal Samy Sayed Mohamed Yassin
M.D

Professor of Cardiothoracic surgery
Faculty of medicine- Ain Shams University

Doctor / Osama Abbas Abd Elhameed Abo Elela
M.D

Assistant Professor of Cardiothoracic surgery
Faculty of medicine- Ain Shams University

Doctor / Sherif Abdel-Samie Ahmed Mansour
M.D, FRCS (Cth)

Lecturer of Cardiothoracic surgery
Faculty of medicine- Ain Shams University

Faculty of medicine- Ain Shams University

2016

ACKNOWLEDGEMENT

ACKNOWLEDGEMENT

I am deeply grateful to *Prof. Dr.* ***Gamal Samy Sayed Mohamed Yassin,*** professor of Cardiothoracic surgery – Faculty of medicine, Ain Shams University, who gave me his experience, advice and guidance.

I would like to thank *Prof. Dr.* ***Osama Abbas Abd Elhameed Abo Elela,*** professor of Cardiothoracic surgery - Faculty of medicine, Ain Shams University for his generous support and continuous encouragement.

I faithfully thank *Dr.* ***Sherif Abdel-Samie Ahmed Mansour***, Lecturer of Cardiothoracic surgery - Faculty of medicine, Ain Shams University, for his endless guidance, kind help, and overwhelming support.

I would like also to thank all the staff members of the Cardiothoracic Surgery department, Ain Shams University and all my colleagues.

CONTENTS

LIST OF FIGURES

LIST OF TABLES

LIST OF ABBREVIATION

LVAD : Left ventricular assist device

LVADs: Left ventricular assist devices

HF : Heart failure

VADs :Ventricular assist devices

VAD :Ventricular assist device

FDA :Food and Drug Administration

MCSDs : Mechanical circulatory support devices

LVAS :Left ventricular assist system

IVAD :Implantable ventricular assist device

MCSD : Mechanical circulatory support device

PVAD :paracorporeal ventricular assist device

BTT: Bridge to transplantation

BTR: Bridge to recovery

REMATCH : Randomized Evaluation of Mechanical Assistance in Treatment of Chronic Heart Failure

NYHA: New York Heart Association

HVAD: Heart Ware ventricular assist device

DT: Destination therapy

INTERMACS : Interagency Registry for Mechanically Assisted Circulatory Support

CUBS : The Clinical Utility Baseline Study

INTrEPID : **I**nvestigation of **N**ont**r**ansplant **E**ligible **P**atients Who Are **I**notrope **D**ependent

TNF-α : Tumor Necrosis Factor alpha

LV : Left ventricle

HARPS : Harefield Recovery Protocol Study

LVEF : Left ventricular ejection fraction

NYHA: New York Heart Association

RVAD: Right ventricular assist device

BiVAD: Bi Ventricular assist device

TAH: Total artificial heart

REVIVE-IT: Randomized Evaluation of VAD InterVEntion before Inotropic Therapy)

RV: Right ventricle

TAPSE : Tricuspid annular plane systolic excursion

STS : Society of Thoracic Surgeons

CABG : Coronary artery bypass graft surgery

BTC : Bridging to candidacy

ECMO: Extracorporeal membrane oxygenator

MEDAMACS : Medical Arm of Mechanically Assisted Circulatory Support

US: United States

Abstract

MCS continues to be one of the most dynamic therapies in medicine and, as reported in this essay, is being studied extensively across the globe to ensure optimal outcomes.

Durable devices are under the most intense investigation with a shift in focus from survival to a reduction in adverse events and minimizing negative patient –device interactions. At the forefront of this will be a further study into the growing problem of LVAD thrombosis, which was highlighted in a special edition of the Journal of Heart and Lung Transplantation and a high-profile study by leading U S. centers.(182)

Factors studied as part of this process will include patient, device, and practice variables but will also require careful assessment of current and future regulatory oversight in MCS therapy

Key words:
heart failure; heart assist device; prognosis, Ventricular assist device, VAD, Pathology, Device regulation recommendations, Artificial organs, Ventricular assist device, Rotary blood pump

CHAPTER ONE

INTRODUCTION
&
HISTORY OF LVAD

Introduction
&
History of LVAD

No other field in cardiology is experiencing such explosive growth as mechanical circulatory support for advanced heart failure (HF). As increasing numbers of patients become refractory to optimized medical therapy, the need for definitive treatment modalities grow. Previously, the only proven treatment for these patients was heart transplantation. While the number of transplants has reached a plateau at 4,500 a year worldwide and 2,200 per year in the United States, growth in the number of recipients of long-term ventricular assist devices (VADs) is accelerating . Estimates of potential recipients for VAD support vary widely, confounded by liberal use of definitions like “refractory HF,” “advanced HF,” and “stage D” HF, as well as changing indications for implantation. In some communities, the prevalence may be as low as 0.2% of the general HF population (1)

Historically, John Gibbon in 1953 was the first to introduce the idea of mechanically supporting the cardiopulmonary system, when he successfully used cardiopulmonary bypass for an atrial septal defect repair (157).

The first ventricular assist device was implanted in 1963 by DeBakey in a patient suffering a cardiac arrest following aortic valve replacement. The patient subsequently died on the fourth postoperative day. Nevertheless,

DeBakey reported in 1966 the first successful implantation of a pneumatically driven VAD as bridge to recovery for 10 days in a patient sustained postcardiotomy shock. The patient ultimately survived to discharge (158).

Cooley reported soon thereafter, the first successful implantation of a pneumatically driven artificial heart as bridge to transplantation (159).

In 1984, DeVries and colleagues performed the first successful implantation of the Jarvik-7-100 total artificial heart (160).

Despite the first promising results, the incidence of thromboembolic and infectious complications remained high leading to a moratorium in 1991 regarding the use of the total artificial heart. However, in 1994, the achieved advances in the development of LVADs culminated in a Food and Drug Administration (FDA) approval of an LVAD as a bridge to transplantation treatment.

First-Generation Mechanical Circulatory Support

The first-generation LVADs were large pulsatile, positive displacement pumps with a lot of moving parts. The devices were limited to patients with a body surface area greater than 1.5m2 and were the first MCSDs initially introduced into clinical practice. The prototypes are the

Novacor left ventricular assist system (LVAS, World Heart, Salt Lake City, Utah, USA), first implanted in a human in 1984 and used successfully as BTT in that patient, the Thoratec IVAD (implantable ventricular assist device) and the Heart Mate XVE (later called Heart Mate I; Thoratec Corporation, Pleasanton, Calif), which was first tested in a

clinical trial in 1986 (161,162).

The HeartMate XVE is the only long-term implantable MCSD not requiring systemic anticoagulation therapy, while the Thoratec IVAD is the only implantable MCSD approved for biventricular support. Regarding the site of pump implantation commonly utilized pulsatile-flow MCSDs, in which the blood pump lies external to the patient are the Thoratec PVAD (paracorporeal ventricular assist device), the Berlin Heart Excor (Berlin Heart AG, Berlin, Germany) and the Toyobo LVAS (Toyobo Co Ltd, Osaka, Japan) fulfilling indications for temporary use

for the BTT and BTR . The clinical performance of MCSDs is evaluated in several studies. The landmark of those is the Randomized Evaluation of Mechanical Assistance in Treatment of Chronic Heart Failure (REMATCH) study, which evaluated the HeartMate XVE assist device compared to medical treatment in patients with end-stage heart failure(163).

This series consisted of 129 patients with heart failure of New York Heart Association (NYHA) class IV not fulfilling indications for heart transplantation. The study population was randomized to receive either a HeartMate XVE or maximum medical treatment. The 1-year survival was in the assist device group with 52% significantly higher compared to the medical treatment group, which showed a survival at

1 year of 25% and after 2 years 28% versus 8%, respectively. Major drawbacks, of the HeartMate XVE, are its large size, high device failure and infection rate of 17% and 41% respectively at 18 months of continued use (164). A study of 280 patients after HeartMate XVE implantation performed by Lietz and colleagues confirmed the outcomes of the REMATCH study (165).

Despite an 1-year survival of 56%, the postsurgical early mortality and device failure rate at 2 years were fairly high at 27% and 73%, respectively.

Similar results regarding survival provided the nonrandomized series of Rogers et al., which evaluated the performance of the Novacor LVAS. The LVAD treatment led to improved survival compared to the medical therapy, but was associated with neurologic complications approaching a stroke risk rate of 62% (167).

The first-generation MCSDs have been supplanted by newer devices because of their high device-related complications such as infections and mechanical failure arising from their large size and the complexity of the pump function.

Second Generation Mechanical Circulatory Support

The second-generation MCSDs consisted of axial pumps, which utilize continuous rather than pulsatile blood flow without valves. This continuous pulseless blood flow is physiologically entirely well-tolerated and pulseless LVADs support improves neurocognitive disturbances due to severe heart failure, just as pulsatile devices do (168).

The presence of a single-moving rotor minimizes device wear and tear resulting to mechanical stability for years. Additionally, their