

Incidence, causes, severity and short term outcome of paravalvular leak in patients with prosthetic cardiac valves

MSc Thesis

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BY

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Their words of inspiration and encouragement still linger on

.....To my parents

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List of abbreviations

ACC/AHA	American college of cardiology/American heart association
ADO	Amplatzer ductal occlusion
AR	Aortic regurge
ASE	American society of echocardiography
ASO	Amplatzer septal occlusion
AVP	Amplatzer vascular plug
AVR	Aortic valve replacement
CHF	Congestive heart failure
CPB	Cardiopulmonary By-Pass
CTA	Computed tomographic angiography
CT	Computed tomography
CW	Continous- wave
DVI	Doppler velocity index
ECG	Electrocardiogram
EOA	Effective orifice area
EROA	Effective regurgitant orifice area
HF	Heart failure
ICE	Intracardiac echocardiography
LA	Left Atrium
LV	Left Ventricle
LVO	Left Ventricle outflow
MR	Mitral Regurge
mVSD	Muscular Ventricular Septal Defect
MVR	Mitral valve replacement
NYHA	New York Heart Association
PHT	Pressure half time

PPM	Patient Prosthesis mismatch
PVL(S)	Pravalvular leak(s)
PR	Pulmonary Regurge
PW	Pulsed- Wave
RF	Regurgitant Fraction
RV	Right ventricle
Rvol	Regurgitant Volume
TOE/TEE	Transoesophageal echocardiography
TR	Tricuspid Regurge
TTE	Transthoracic echocardiography
VC	Vena Contracta
Vs	Versus
VTI	Velocity time integral
VTI _{LVO}	Velocity time integral through Left Ventricle Outflow
VTI _{prMV}	Velocity time integral through Prosthetic Mitral valve
VTI _{prV}	Velocity time integral through Prosthetic valve
2-D	2 dimension
3-D	3 dimension
4-D	4 dimension

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Abstract

Objective: the aim of this study is to report the incidence, causes, severity, and short term outcome of early paravalvular leak in patients with prosthetic cardiac valves

Methods: this is a prospective observational study included 200 patients who underwent valve replacement surgery from May 2014 to May 2015, aortic in 77, mitral in 80, combined aortic and mitral in 43 patients. Clinical evaluation, laboratory investigations, and echocardiography were performed for all patients. Follow up echocardiography was performed for patients with paravalvular leak to follow up severity. Statistical comparisons were performed to determine correlates of paravalvular leak

Results: early paravalvular leak occurred in 3.75%, 9%, and 35% of patients who underwent mitral valve, aortic valve, and combined mitral and aortic valve replacement respectively. Infective endocarditis, renal impairment, prior mitral and/or aortic valve replacement were important correlates where they were found in 16(64%), 3(12%), 17(68%) and 22(88%) patients with early paravalvular leak with $P = <0.001$, 0.027, < 0.001 , < 0.001 respectively. Paravalvular leak on mitral prosthesis was mild, moderate, and severe in 6 (67%), 1 (11%), and 2 (22%) patients respectively. Paravalvular leak on aortic prosthesis was mild, moderate, and severe in 8 (42%), 4 (16%), and 8 (42%) patients respectively. Early postoperative mortality occurred in 4 (16%) of patients with paravalvular leak after redo surgery due to sepsis.

Conclusion: Paravalvular leak is still an important complication of both mitral and aortic valve replacement. Prior valve(s) replacement, preoperative diagnosis of infective endocarditis, and presence of renal impairment were important correlates for paravalvular leak. Surgery should be done in patients with severe PVL as the prognosis is poor without surgery

Key words: paravalvular leak, echocardiography, infective endocarditis

Introduction

HEART valve replacement is the second most common type of cardiothoracic surgery after coronary artery bypass graft surgery.¹

The presence of paravalvular leaks (PVLs) is a well-known complication after both aortic (AVR) and mitral (MVR) valve replacements. It occurs because of the incomplete apposition of the sewing ring to the native annular tissue. PVLs can be seen either immediately after valve replacement in the operating room or during the follow-up period. The immediate PVLs usually are associated with technical difficulties related to calcification of the native annulus. Late PVLs are commonly a consequence of suture dehiscence caused by prosthetic valvular endocarditis or gradual reabsorption of incompletely debrided annular calcifications.^{2, 3}

Although there is widespread agreement among cardiologists and surgeons that severe PVLs should be corrected immediately, there is no consensus regarding the optimal management of patients with mild-to-moderate PVLs. In many of these cases, the risk of untreated PVLs has to be balanced against the consequences of prolonged cardiopulmonary bypass (CPB) time, which may carry significant incremental risks.

Although clinical deterioration over time has been reported in patients with mild and moderate PVLs, it is less clear which particular individuals are at higher risk.⁴ Furthermore, there are several reports describing the incidence of perioperative detection of PVLs after valve replacement surgery; however, there is a paucity of data regarding the PVLs and their association with immediate postoperative outcomes.^{5, 6}

Aim of the work

1. To evaluate the incidence, causes, severity and short term outcome of early paravalvular leak in patients with prosthetic cardiac valve.
2. To describe association of hemolytic anemia to different grades of paravalvular leak.

Chapter 1

Prosthetic heart valves

Historical evolution of prosthetic heart valves

Albert Starr and Alain Carpentier, were the main contributors to the development of the prosthetic heart valve, which represents a milestone in the journey toward the fabrication of synthetic living tissues and organ systems. The prosthetic heart valve was built on a foundation laid down during the first half of the 20th century with the introduction of cardiac catheterization by André Cournand and Dickinson Richards, the development of innovative surgical techniques by Alfred Blalock, the invention of the heart–lung machine by John Gibbon, and the discovery of heparin by Jay McLean and dicumarol by Karl Paul Link. In the late 1950s, as clinical practice was being linked more closely to the surgical laboratory and collaborations were established with those working in the nascent field of biomedical engineering, new intellectual and technical frameworks were created for replacing dysfunctional organ components with biologic or synthetic prostheses⁷

In 1954, Charles Hufnagel and his colleagues described 23 patients with aortic insufficiency that had been treated during the previous 2 years by rapid insertion of an acrylic ball valve into the descending aorta.⁸ (figure 1), However, since the valve prevented regurgitant flow only from the lower body, cardiac work was only partially relieved and coronary flow was not improved. In addition, embolization and thrombosis of the valve occurred frequently, and the noise generated by the valve was disconcerting. Nevertheless, Albert Starr and Dwight Harken recognized the importance of this approach and the advantage of using durable, rigid components, and they persisted in developing a caged ball valve. On September 21, 1960, Starr performed the first successful orthotopic valve replacement in the mitral position, which was followed by Harken's implantation of prosthesis in the aortic position.^{9, 10} Design criteria were

formulated. The materials had to be chemically inert, compatible with human tissue, atraumatic to blood, and nonthrombogenic. They also had to retain their structural properties over many years and lend themselves to being engineered into a valve that was acceptable to patients, opened and closed rapidly in response to changes in the pressure gradient, and resulted in limited obstruction to forward flow and minimal regurgitation in the closed position. Finally, it had to be technically feasible to implant the prosthesis securely in an appropriate physiologic position.

Enthusiasm for mechanical valves was tempered by their association with persistent thromboembolic complications. The ball-valve prosthesis developed by Starr and M. Lowell Edwards, a mechanical engineer (Figure 1), underwent various design changes after its introduction to reduce its thrombogenic potential. The amount of exposed metal was reduced, the material compositions changed, the surfaces coated with heparin, the design modified to facilitate retrograde flow that could “scour” the components, and the fabric altered in an effort to induce growth of endothelium. Some of these changes created new problems, including fraying of the fabric, excessive ingrowth of tissue, and obstructed blood flow. Overall, the embolization rate was reduced, but patients continued to require permanent anticoagulant therapy.⁷

Mechanical valves were refashioned in the late 1960s, when a tilting disk was introduced to minimize resistance to forward flow, decrease turbulence, limit regions of stagnation, and reduce shear stress. Although thromboembolism was not eliminated, anticoagulation requirements were reduced. In 1977, the ideal of central unimpeded flow was approached with the advent of the bileaflet valve. Despite improved hemodynamics and the application of thromboresistant alloys and advanced ceramics, the goal of substituting the use of antiplatelet agents for lifelong anticoagulant therapy remains elusive.⁷

The hemodynamic and biologic advantages of cadaveric heart valves became evident in 1962 after Donald Ross implanted the first aortic-valve allograft in the subcoronary position, but their limited supply necessitated a search for other tissue substitutes.¹¹ Subsequent reports from Australia and Britain confirmed these