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Original Research Article

A PROSPECTIVE STUDY ON TTK CHITRA HEART VALVE PROSTHESIS IN CARDIAC PATIENTS: A HOSPITAL BASED STUDY IN KARNATAKA

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Abstract

Introduction: The TTK Chitra™ heart valve (TTKCHV) developed by the Sree Chitra Tirunal Institute for Medical Sciences and Technology, Trivandrum , and manufactured by TTK Healthcare Limited is used in a large number of centers dealing with rheumatic heart disease (RHD). A number of clinical studies that have been published over the last 25 years clearly show the valve to be as good, if not better, than many of the currently imported mechanical valve models. The introduction of valve replacement surgery in the early 1960s has dramatically improved the outcome of patients with valvular heart disease.

Materials and Methods: A 255 patients with implantations from Feb 2021 to Jan 2023 were followed up prospectively consisting of 50 aortic valve replacement (AVR), 87 double valve replacement (DVR), and 113 mitral valve replacement (MVR) patients ,being 96% complete.

Results: The results showed that 82.3% for AVR, 60.7% for MVR, and 52.2% for DVR. Freedom from all valve-related mortality at 15 years was 73.8%, 64.8%, and 61.9% for AVR, MVR, and DVR, respectively.

Conclusion: The results highlight the continued safety and performance of the TTK Chitra™ heart valve (TTKCHV) in the long term.

Keywords: TTR Chitra heart valve, Heart Valve Prosthesis

Introduction

The TTK Chitra™ heart valve (TTKCHV) developed by the Sree Chitra Tirunal Institute for Medical Sciences and Technology, Trivandrum , and manufactured by TTK Healthcare Limited is used in a large number of centers dealing with rheumatic heart disease (RHD). A number of clinical studies that have been published over the last 25 years clearly show the valve to be as good, if not better, than many of the currently imported mechanical valve models.The introduction of valve replacement surgery in the early 1960s has dramatically improved the outcome of patients with valvular heart disease. 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. 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

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thrombogenicity. 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. The purpose of this article is to provide an overview of the current state of knowledge and future perspectives with regard to optimal prosthesis selection and clinical management after valve implantation. Some patients who underwent valve replacement with the original Starr-Edwards prosthesis in the 1960s are alive to this day. The Starr-Edwards ball and cage prosthesis, albeit in modified form, is still available commercially. Each year more than 6000 patients in the UK and 60 000 in the USA alone undergo valve replacement surgery. In the last 40 years more than 80 models of prostheses have been developed for patients requiring valve replacement.[1-7]

Materials and Methods

A 255 patients with implantations from Feb 2021 to Jan 2023 were followed up prospectively consisting of 50 aortic valve replacement (AVR), 87 double valve replacement (DVR), and 113 mitral valve replacement (MVR) patients being 96% complete. All echocar diography examinations were performed by a senior echotechnician and cross checked by the second author. Patients who were reluctant to attend the follow-up clinic due to personal reasons or the prevailing coronavirus infectious disease (COVID)-19 pandemic were contacted over phone and their clinical status was collected to the extent feasible using a questionnaire. In case of death, all available information, including any possible relationship to the device, was collected from hospital records or close relatives. Informed consent was obtained from the guardians, who consented for the detailed follow-up. Blood investigations, New York Heart Association (NYHA) functional class assessment, hemodynamic performance, and any event post valve implantation were recorded. Ten patients who were not willing to visit the hospital due to the coronavirus infectious dis- ease (COVID-19) pandemic were contacted over phone andclinical information was collected using a questionnaire.

Results

The mean age of the entire cohort was 30-65 years at the time of surgery (Table 1). Twelve AVR patients had a total 107 patient-years of follow-up; the oldest was a 76-year-old female AVR patient (Table1). (median 40 years; interquartile range (IQR) 30–48). ANOVA performed on age and weight between the three valve replacement groups showed that there is no significant difference in age ($p = 0.81$) while dif- ference in weight was significant ($p = 0.02$) among the AVR- MVR and MVR-DVR group. In total, 48.9% of patients had comorbidities, 46.4% had co-existing cardiovascular dis- eases, and 23.1% had previous valve surgeries. (Table 2)

Table 1:

Study details	AVR	MVR	DVR	Total
Etiology				
Mitral stenosis	0	69	20	89
Mitral regurgitation	30	73	19	122
Mitral mixed	3	13	44	60
Aortic stenosis	17	1	4	22
Aortic insufficiency	46	42	43	131
Aortic mixed	39	0	39	78

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AVR aortic valve replacement, *MVR* mitral valve replacement, *DVR* double valve replacement, *N* number of patients, *y* years, *SD* standard devia- tion, *CLD* chronic liver disease, *CAD* coronary artery disease, *CHF* congestive heart failure, *PVD* peripheral vascular disease, *MI* myocardial infarction, *OMV* open mitral valvotomy

Table 2:

Prosthesis sizes used

Valve size	Aortic valves used (total, $N = 192$) AVR (104) and DVR (87)			
	No. of valves	% of total AVR ($N = 192$)	No. of valves	% of total MVR ($N = 371$)
17 mm	12	6.3	0	0
19 mm	59	30.7	0	0
21 mm	46	24	0	0
23 mm	43	22.4	14	3.8
25 mm	28	14.6	80	21.6
27 mm	2	1	113	30.5
29 mm	2	1	81	21.8
31 mm	0	0	83	22.4
33 mm	0	0	0	0

Mitral valves used (total, $N = 371$) MVR (284) and DVR (87)

AVR aortic valve replacement, *MVR* mitral valve replacement, *DVR* double valve replacement, *N* number of patients

One 17-mm aortic valve implanted in mitral position

Discussion

Three papers have reported follow-up results of TTKCHV up to 10 years. Sankarkumar et al. [3,6-10]reported the follow-up of the first multi-center cohort of 306 patients from December 1997 to March 1998 and covered survival at 7 years and linearized incidence of valve-related complications, etc. Muralidharan et al. [5]reported the 10-year outcome of 65 patients (who were part of the same first cohort as in the.The ISO standard for surgically implanted heart valve substitutes [8]mentions that OPC are the average linearized complication rates derived based on an analysis of the safety and effectiveness data submitted by manufacturers in pursuit of premarket approval of bioprosthetic and mechanical valves combined with an analysis of literature from 1999 to 2012 .Hence, a comparison between the linearized rates of valve-related events with the OPC was performed. The lower linearized rates here highlight the continued safety in the long-term performance of the TTKCHV. The current complication rates for thrombosis, thromboembolism, and bleeding were lower than the rates reported during the first clinical trial of TTKCHV during the 1990s. Data show that the difference in linearized rates of complications was statistically significant (p = 0.04). Despite improvements in testing and anticoagulant management, nearly 70% (167 patients) who attended the follow-up clinic had INR values outside the recommended control range. In this study group, 132 patients had INR below the target range. One hundred thirty-two patients (20 AVR, 86 MVR, and 26 DVR) who were followed up had INR values below the therapeutic range of 2–3 for AVR and 2.5–3.5 for MVR and DVR. In the AVR group, 6 patients had INR between 1.5 to 2 while 18 had INR between 1.0 and 21.5. The average of

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low INR for aortic patients was 1.57. In the MVR/DVR group, 47 patients had INR between 2 and 2.5, 35 had between 1.5 and 2, and 29 had between 1 and 1.5. The average low INR value for MVR/DVR group was 1.45 and the lowest recorded INR value was 0.94. Even with these lower levels of anticoagulation in this cohort, the incidence of valve-related complications, particularly valve thrombosis and thromboembolism was below the internationally reported levels. This brings up the question as to whether the current internationally recommended target INR levels which are being followed in India are suitable for Peak and mean gradient measurements for 244 patients showed that the hemodynamic performance of TTKCHV is comparable to the values reported earlier [11-14]and other well-known mechanical valves (tilting disc and bileaflet) as published by the American Society of Echo- cardiography [15]. Nagarajan et al.[16]reported com- parable hemodynamic performance and gradients across the TTKCHV to other mechanical valves. Namboodiri et al. [17studied] the Doppler echocardiography param- eters obtained with the TTKCHV in the mitral position and found that it was comparable to different prosthetic valves in common use. The valve gradients and EOA, as measured by echocardiography, showed consistent performance of TTKCHV in comparison t. Three of the six patients implanted with 17-mm aortic valve belonged to pediatric population which leads to PPM in these patients.

Conclusion

The TTKCHV continues to be a safe and effective mechanical heart valve for the replacement of diseased heart valvesas evidenced in this long-term clinical study

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