

Clinical Profile and the Factors Associated With Outcomes among Patients Implanted With Indigenous Prosthetic Heart Valve

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Abstract : Heart valve replacement is a definitive surgical procedure performed in a selective set of patients having heart valve disease. Though there are innumerable designs and types of prosthetic valves being used , there is no single ideal prosthetic valve which has equal the durability and efficiency of a natural valve and the search for an ideal prosthetic heart valve is still continuing in various parts of the world.

Keywords: Rheumatic Heart disease, Prosthetic valve, Valve replacement

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I. Introduction

Heart valve replacement is a definitive surgical procedure performed in a selective set of patients having heart valve disease. In India RHD forms the major portion of cases 1,2 undergoing valve replacement surgery , either in mitral or Aortic positions and less commonly for Tricuspid valve. Though there are innumerable designs and types of prosthetic valves being used , there is no single ideal prosthetic valve which has equal the durability and efficiency of a natural valve and the search for an ideal prosthetic heart valve is still continuing in various parts of the world. The choice of valves are either bio-prosthetic valves, made from a biological tissue source or mechanical valves, each having their own merits and demerits . The technique of valve replacement surgery had undergone many modifications with the help of modern advancement in the field of Bio-medical engineering and evolving medical technologies in various parts of the world. In India, type of a mechanical tilting disc valve type, which is totally indigenous, was developed at Sri Chitra Thirunal Institute of medical sciences and technology at Trivandrum in kerala, the TTK chitra valve

II. Methodology

PATIENTS AND METHODS

The study was a hospital based , Prospective study done in patients who underwent valve replacement surgery with TTK chitra valve in the department of CardioThoracic and Vascular surgery JIPMER , Pondicherry from Dec 2016 to Jan 2018 after obtaining clearance from Institute Research committee and Institute Ethics committee

INCLUSION CRITERIA

All patients who underwent valve replacement after 2008 and above 18 years of age with TTK chitra valve attending JIPMER OPD and EMS.

EXCLUSION CRITERIA

Patients who underwent mitral and aortic valve repair

SAMPLING:

Sampling population

All patients underwent valve replacement above 18 years of age after 2008 satisfying the inclusion and exclusion criteria.

SAMPLE SIZE :

A total of 250 patients implanted with TTK chitra valve, satisfying the inclusion and exclusion criteria attending the CTVS outpatient department and Emergency medical services were included in this study

STUDY PROCEDURE :

All patients who underwent indigenous valve replacement in our hospital satisfying the inclusion criteria and attending the CTVS outpatient department for regular check up , emergency services and valve clinic follow up were included in this study. All patients were allocated a specific number to avoid repeating the sampling in the same patient.

1. Socio demographic parameters and surgery related data are recorded from the discharge summary and surgical registry as given in annexure A .
2. A questionnaire method is used to evaluate clinical profile and valve related parameters as given in annexure B , C.
3. Clinical examination findings are recorded as in Annexure B.
4. The current post operative profile is assessed from the Investigations like ECG , CXR , ECHO when indicated , PT/INR and other relevant data from the case sheets and Hospital online resources as mentioned in Annexure D. The Following associated factors that influence the surgical outcomes of the patient are recorded.
 1. Age and age at the time of surgery.
 2. Length of hospital stay.
 3. Surgical procedure .**
 4. Comorbidities such as Diabetis Mellitus, hypertension , COPD, Coronary artery disease ,Thrombo embolism,hypothyroidism etc .
 5. Elective or emergency .**
 6. Prothrombin time and International normalised ratio[INR].
 7. Warfarin or Acitrom dosage.
 8. Pre-op valve status [ECHO].

OUTCOMES:

I.a. Independent variables [annexure A]

1. Socio-demographic profile : age, gender , co- morbidity , occupation.
2. Age at the time of surgery.
3. Elective or emergency operation.
4. Surgical procedure
5. Length of hospital stay
6. Pre-op valve status[ECHO]

I.b. Outcome variables

1. Clinical profile of the patient [Annexure B]
2. Valve related complications[Annexure C]
3. Valve profile [Annexure D]

STATISTICAL ANALYSIS

The distribution of categorical variables such as gender , socio-demographic characteristics , surgical characteristics , clinical characteristics and others will be expressed as frequency and percentages . The continuous data such as Age , age at implantation , biochemical parameters will be expressed as Mean with S.D or median with range. The association of the clinical profile with other categorical variables mentioned above will be carried out by using Pearson's chi-squared test (χ^2) or Fishers exact test . The comparison of the continuous variables between the clinical profiles will be carried out by using Independent student t test / Mann whitney U-test or one way analysis of variance / Kruskal-Wallis test whichever is appropriate based on the distribution of data and number of groups .The independent factors associated with the clinical profile will be expressed by using the binary logistic regression analysis or multinomial logistic regression analysis . All the statistical analysis will be carried out at 5% level of significance and P value < 0.05 will be considered as significant.

III. Discussion

The study group comprises of the patients who had undergone TTK Chitra valve replacement surgery, performed at JIPMER after 2008. Most of the patients at the time of surgery were in the age group 31 to 40 years (80 patients).The mean age at the time of surgery was 37.17 years, which is consistent with other studies

performed in the south indian population [16]. Rheumatic heart disease is the major cause of the valvular heart disease in this study . Females (65.2%) were more commonly affected than males [16, 21]. About 191 patients (76.4%) were free of any pre-operative co-morbidity and 59 patients (23.6%) were with various types of pre operative comorbidities. As the mean age group of the patients was 37.7 years at the time of surgery, there was less incidence of Diabetes mellitus, Hypertension and Coronary artery diseases accounting for a total of only 11.6% patients.

A total of about 242 patients (96.8%) were taken for elective valve replacement and 8 patients (3.2%) were taken for emergency valve replacement [stuck valve (4), Acute chordal rupture with MR(1) and Post mitral balloon valvotomy (3)]. The less number of patients in the emergency group suggests better performance of the valve replaced patients with less incidence of prosthetic valve related complications that requires redo surgery.

The mean duration of hospital stay was 15.04 days. This mean hospital stay was between the date of surgery to date of discharge. All the patients were stabilised in the immediate post operative period in the intensive care unit . After the ICU stay patients were shifted to the post operative ward and kept there until the INR values reached therapeutic range (As the patient population is from very poor socioeconomic background and coming from distant places), and postoperative Echocardiogram showing satisfactory results .All the immediate postoperative complications were addressed and were provided with valve booklet along with sensitization regarding anticoagulation.

There was a close association between the angina and the type of surgery ($p = 0.00$).

Even though 89.2 % patients were free of angina, a small subset of 10.8 % had angina. Angina was more common among the mitral valve replacement(4.4%) patients followed closely by the aortic (4.0%) and double valve replacement patients

IV. Conclusion

Rheumatic heart disease was the most common cause of valvular heart diseases and Mitral valve was the most commonly affected and also replaced valve. The clinical profile of the patients implanted with TTK chitra valve was stable without major limitation in their daily activities. The valve profile of the TTK chitra valve shows good haemodynamic performance in the postoperative period.

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