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Original Article

Evaluation of Anticoagulant Use in Post Valvular Heart Surgery in Relation with International Normalised Ratio (INR) and Valve Replaced

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ABSTRACT

Background: Valvular heart disease is a growing concern worldwide. Patients diagnosed with valvular heart disease are majorly indicated for valve replacement or repair surgery which may lead to thromboembolic events. To prevent these thromboembolic events anticoagulants and antiplatelets are usually prescribed, but use of these agents on the other hand may lead to bleeding events, hence optimal INR range needs to be maintained. **Purpose:** Our study aimed to analyze the optimal INR range for patients with different types of valve replacements and to assess use of anticoagulants in patients after valve replacement. **Materials and Methods:** This study is a prospective, observational with a total sample size of 108 who underwent valve replacement were considered. Pre-designed data collection forms were used to collect specific data. All parameters were categorized into continuous variables and categorical variables and were then evaluated. **Results:** Out of 108 patients 45 were males 63 were females with mean age of 43.87±15.94. A total of 58% patients had problem associated with mitral valve and 22% had problems with aortic valve. Rest came with complaints in multiple valve. Out of 108 patients 100 (92%) patients were indicated for mechanical valve implant and 08 (8%) patients were indicated for tissue valve implant. All 108 patients were given with acitrom as an anticoagulants with varying daily doses depending on their daily INR values. Optimal INR range varied based on type of valve affected and type of valve implanted and was found to be statistically significant (p=0.0023). Out of 108 patients 96 (89%) were given with antiplatelet agent (aspirin) along with anticoagulants and 12 (11%) were not given with antiplatelet agent due to increased risk of bleeding. **Conclusion:** From the present study it is evident that the most common valve affected was mitral valve with varying pathology of stenosis, regurgitation and combination of both. Mechanical valve was used more in comparision to prosthetic valves for valve replacement. Anticoagulation is necessary along with use of antiplatelet agent to prevent thromboembolic events in post valvular surgery. INR values to be maintained varied based on type of valve replaced, mechanical valves required maintenance of higher INR value because of increased risk of thromboembolic events.

Keywords: Valvular heart surgery, INR, Vitamin K antagonist, Antiplatelet agent, Bioprosthetic valve, Mechanical valve.

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INTRODUCTION

Valvular heart disease is a growing concern with rapidly increasing prevalence which occurs due to defects in heart valves, which are responsible for controlling blood flow direction throughout the heart. Each valve's function is to close and prevent blood from flowing backward (regurgitation), ensuring the proper mixing and continuous flow of blood throughout the heart. Heart valve disorders arise from two primary issues: regurgitation (valve leakage) and stenosis (valve narrowing). Management of valve abnormalities are usually done by surgical interventions like valve repair and valve replacement. Valve repair encompasses various techniques aimed at restoring optimal valve function and structure. Repair strategies include patching defects or tears, reshaping valve architecture, and manipulating valve leaflets. Valve replacement is a surgical procedure performed when a heart valve is severely damaged or diseased and cannot be effectively repaired. The defective valve is removed and replaced with either a mechanical valve or a biological valve, chosen based on individual patient factors and discussions with healthcare providers.

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Thromboembolic events are usually seen in first three months post-surgery in case of both mechanical and prosthetic valves. Patients on mechanical valve are always at higher risk of thromboembolic events. Hence anti thrombotic therapy post valve surgery is very important in reducing morbidity and mortality.

Among various anticoagulants (antithrombotic therapy), use of vitamin k antagonist with regular monitoring of target INR was found to be most effective. Patients prescribed with anticoagulants are always at higher risk of thrombosis and bleeding hence their INR needs to be monitored and maintained on a regular basis.

Various guidelines have been established to provide target INR range after valve surgery like Good Clinical Practice Recommendation (GCPR) from Indian Association of Cardio Vascular Thoracic Surgeons (IACTS), American College of Chest Physician (ACCP) guideline for use of VKA therapy and ACC/AHA guidelines for use of VKA Therapy.[1-8] In this study patients were given with Acitom as an anticoagulant (Vitamin K antagonist) along with antiplatelet therapy with Aspirin to prevent thromboembolic events associated with post valvular heart surgery. As the patients are on anticoagulant therapy monitoring of INR was done to prevent any bleeding events. The current knowledge on research area throws light on importance of antithrombotic therapy after valve replacement, complications associated with long term use of antithrombotic therapy and importance of consistant INR monitoring in preventing bleeding risk. There are very few studies which provide real world data for optimal INR which needs to be maintained for different types of valve replaced based on the various guidelines. The main purpose of the study was to analyse the antithrombotic therapy use and to monitor the INR values in different cases of valve replacement thereby identifying the optimal INR range.

AIM

To evaluate the anticoagulant use in post valvular heart surgery in relation with INR and valve replaced.

OBJECTIVES

The primary objective of this study is to identify the most commonly affected heart valve along with its associated pathology. Additionally, the study determines the most frequently replaced type of valve in clinical practice. An important focus is also placed on evaluating the INR ranges based on the specific valve that has been replaced. Furthermore, the study seeks to assess the pattern of anticoagulant usage among patients following valvular heart surgery, thereby providing insights into postoperative management and anticoagulation strategies.

MATERIALS AND METHODS

Study Design

Prospective observational study.

Duration

6 months.

Setting

Department of Cardiothoracic and Vascular Surgery (CTVS), Geetanjali Medical College and Hospital, Udaipur.

Sample Size

108 patients.

Sample size calculation

Using Cochran's formula:

$$N = z2pq / e2,$$

At 95% confidence level, 5% absolute error,

Prevalence = 7.6 % of Rajasthan,

Z=1.96

E= 5%= 0.005

p=7.6% = 0.076

Q= 1-p=1-0.0776= 0.924

$N=z^2pq / e^2$

=(1.96) 0.076 *0.924/ (0.005)2

=3.8416*0.0076*0.924/ 0.0025

=0.269/0.0025=107.9 =108.

Inclusion Criteria

- Patients diagnosed with valvular heart disease indicated for valve replacement surgery.

Exclusion Criteria

- Patients with any other type of heart disease.
- Other concurrent cardiac surgery procedures and non-cardiac surgery procedures.

Data Collection

- Pre designed data collection forms were used to collect patient demographics, valve pathology, type of valve replaced, and anticoagulant therapy details.
- INR values were collected on a daily basis to obtain optimal INR range.

Ethical Considerations

- Approved by the Institutional Ethics Committee (Ref. No. GU/HREC/EC/2023/2378).
- Written and verbal informed consent obtained from all participants.

Statistical Analysis

- Data was analyzed using SPSS software.
- Mean and standard deviation was calculated for continuous variables (INR range) and further significance was estimated using one-way ANNOVA.
- Percentages were calculated for all categorical variables and further significance was estimated using Chi-square test (gender, valve affected, valve implanted, valve pathology, antiplatelet agent, dose of antiplatelet agent).

RESULTS

This study constituted a sample size of 108 in which 42% of total population were males and 58% were female (p=0.1) with a mean age group of 43.87±15.94 (Table 1). Out of 108 patients diagnosed with valvular heart disease majority of them presented with SOB alone (n=55) followed by chest pain along with SOB (n=20), SOB along with palpitations (n=18), chest pain alone (n=7), SOB along with fatigue (n=6) and one each of SOB along with chest pain and fatigue and SOB along with palpitation and chest pain. In majority of the patients diagnosed with valvular heart disease the affected valve was mitral valve (58%) followed by aortic valve (22%). In 6% of the population dual valve was affected (Mitral and aortic), 5% had problem with dual valve along with tricuspid valve and 9% had problem with mitral valve along with tricuspid valve. These observations were found to be statistically significant (p<0.001) as depicted in Table 2. All 108 patients were indicated for valve replacement. 15 patients who had their tricuspid valve affected were indicated for valve repair but they also had dual valve or mitral valve affected hence all 108 patients underwent valve replacement among which 15 underwent both repair and replacement. Type of valve implanted varied as majority of the patients were implanted with mechanical valves when compared to bioprosthetic valves and was found to be statistically significant (p<0.0001) as shown in Table 3. Bileaflet mechanical valve was used for all 100 patients who underwent mechanical valve implant. Valve pathology or the reason for single and multiple valves getting affected also varied amongst this population. Majority of the population had a valve pathology which included a combination of both stenosis and regurgitation followed by stenosis and regurgitation alone. The observed differences in valve pathology were found to be statistically non-significant (p=0.08) as depicted in Table 4. To prevent thromboembolic events all 108 patients who underwent valve replacements were given with anticoagulant specifically vitamin K antagonist (Acitrom) post-surgery.

Maintaining optimal INR in patients administered with vitamin K antagonist is very important in order to prevent bleeding associated with anticoagulant use. The optimal INR range maintained varied based on the type of valve affected and type of valve implanted. Mean INR±SD maintained after anticoagulation in mitral valve replacement with mechanical valve was 2.04±0.68, similarly INR±SD after mitral valve replacement (tissue/bioprosthetic valve), aortic valve replacement (mechanical valve), aortic valve replacement (tissue/bioprosthetic valve), dual valve replacement (mechanical valve), dual valve replacement (mechanical valve) with tricuspid valve repair and mechanical valve replacement with tricuspid valve repair (mechanical valve)

Table 1: Age Distribution.

Age-Group	*n*	Mean±SD
18 - 28	25	43.87±15.94
29 - 38	17	
39 - 48	21	
49 - 58	22	
59 - 68	17	
69 - 78	6	

Table 2: Valve Affected.

Valve affected	*n*	Percentage	*p*-value
Mitral valve	63	58	< 0.001
Aortic Valve	24	22	
Dual Valve	6	6	
DVR+ TV Repair	5	5	
MVR+ TV Repair	10	9	

Table 3: Valve Implanted.

Valve Implanted	*n*	Percentage	*p*-value
Mechanical	100	92	<0.0001
Bioprosthetic	08	08	

were 1.64±0.27, 1.99±0.50, 1.52±0.07, 2.16±0.63, 1.52±0.25 and 2.29±0.83. These observations were found to be statistically significant (p=0.0023) as shown in Table 5 suggesting that type of valve has a significant impact on INR values and is unlikely to be by chance. Along with anticoagulants, majority of the patients (n=96) received antiplatelet agent (T. Aspirin) to prevent chances of thromboembolism and 12 patients were not administered with Aspirin and this observation was found to be statistically significant (p<0.0001). Dose of Aspirin administered also varied among patients, post valvular surgery. 91 patients were given with low dose of Aspirin (75 mg) and 5 patients were given with 150 mg of Aspirin as higher doses of antiplatelet along with anticoagulant may leed to bleeding risks and this observation was found be statistically significant (p<0.0001).

DISCUSSION

Valvular heart disease is found to be one among the most common cause of morbidity and mortality which covers diverse geographic distribution. The major pathology for valvular heart disease were found to be stenosis, regurgitation and combination of both which were evident from ECHO report. Most suitable intervention for treating valvular heart disease was found to be valve replacement, which depends upon the type of valve affected. Prosthetic valves can majorly be classified into 2 types, first one being mechanical valve which is associated with more thromboembolic events and second being tissue valve or bioprosthetic valve which is associated with less thromboembolic events when compared to mechanical valve.[9-17] Development of thromboembolic event is one among the major risk factor associated with valve replacement surgery. Therefore, anticoagulants are used in patients post valve replacement surgery to prevent thromboembolic events. Use of anticoagulants may result in bleeding or hemorrhagic events. To prevent these bleeding events concurrent and regular monitoring of INR with every dose of anticoagulants have been practiced.[18-26]

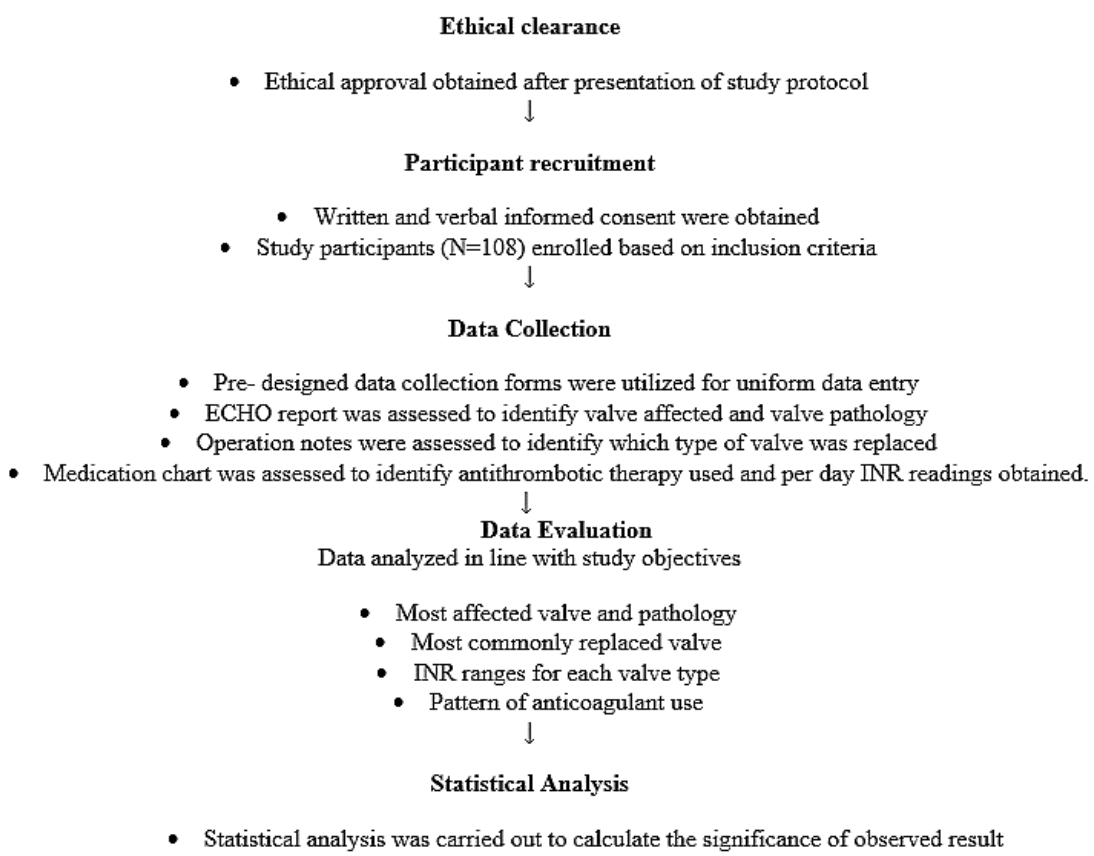
Many studies have concluded that development of valvular heart disease or RHD especially mitral valve pathology happens more commonly in women over men. Results of our study were supported by a similar study which was conducted by Itthidet Kamthorthanaharn *et al.*, on correct INR levels for warfarin therapy after mechanical valve replacement.[27] Mean age of patients in our study was found to be 43.87±15.94. Similar results were reported in a study conducted by Vikrampal Singh *et al.*, who did a analysis on complication related to anticoagulation therapy in patients implanted with prosthetic valve.[4] Valve which is affected can usually be identified using ECHO readings. From our study it is evident that the most common valve getting affected is mitral valve which differed from the study conducted by Gryaznov AA *et al.*, in which aortic valve was getting most commonly affected.[28] The type of valve to be implanted depends on various factors like age, gender, other cardiac conditions, life expectancy, socio-economic factors, risk of thromboembolic events, bleeding complications related to use of anticoagulants and re-operation requirements. From this study it is evident that majority have undergone mechanical valve implantation and very few have undergone bioprosthetic/ tissue valve implantation. Shivkumar Choudhary *et al.*, conducted a similar study where he analysed the benefits of durability of mechanical valve but also mentioned the increased risk of thromboembolic events associated with the use of mechanical valve, which again increases the need of anticoagulation. On the other hand bioprosthetic valve are associated with less incidence of thromboembolic events but has less durability hence indicated for re-operations.[9] There are different types of mechanical valves available in the market like bileaflet, caged-ball, tilting disc. From our study it is evident that bileaflet type of mechanical valve was preferred for mechanical valve implantation. Ying xing *et al.*, conducted a similar study were he described the use of single disc valves and bileaflet valves. Bileaflet valves were associated with lower explantation

Table 4: Valve Pathology.

Valve Pathology	*n*	Percentage	*p*-value
Stenosis	35	33	0.08
Regurgitation	27	25	
Combined	46	42	

Table 5: INR range.

Procedure	*n*	Mean	SD	*p*-value
MVR (Mechanical)	57	2.04	0.68	0.0023
MVR (Tissue)	5	1.64	0.27	
AVR (Mechanical)	21	1.99	0.50	
AVR (Tissue)	3	1.52	0.07	
DVR (Mitral and Aortic) Mechanical	7	2.16	0.63	
DVR+TV Repair (Mechanical)	5	1.52	0.25	
MVR+TV Repair (Mechanical)	10	2.29	0.83	



Conduct of work.

rate.[29] As discussed, earlier role of anticoagulants is to prevent thromboembolic events in patients after valve surgery. In our study all patients (108) were given with vitamin k antagonist (acitrom) at a dose which was varying depending on the INR reading. Most frequently prescribed dose was 3mg, 2.5 mg, 2 mg, 1.5 mg, 1 mg, 0.5 mg and hold where the dose was skipped because of elevated INR. Devendra saxena *et al.*, also concluded in his study that use of vitamin k antagonist with regular monitoring of INR based on target range is necessary in patients who underwent prosthetic valve implantation.[30]

There are several guidelines which provide target INR to be maintained after different types of valve replacement like mechanical valve replacement and tissue/bioprosthetic valve replacement. Good Clinical Practice Recommendation (GCPR) suggests an INR range of 2-3 for mechanical aortic valve replacement and 2.5-3.5 for mechanical mitral valve replacement. Similarly, the range will change if the valve replaced is bioprosthetic. An INR range of 2-3 has been put forward for bioprosthetic aortic and mitral valve replacement.[3] According to American College of Chest Physician (ACCP guidelines) INR range of 2.5-3.5 needs to be maintained for mechanical mitral valve replacement as well as for mechanical dual valve replacement and an INR range of 2-3 for mechanical aortic valve replacement. An INR range of 2-3 for bioprosthetic aortic and mitral valve replacement.[4]

In our study we have obtained optimal INR values which were found to be different for different types of valve replaced which is important for decreasing the bleeding risk post surgery. These values provide a real world data thus emphasizing the need for closer monitoring and adjustment of INR values to ensure that patients remain within therapeutic targets. Good Clinical Practice Recommendation (GCPR) and American College of Chest Physician (ACCP guidelines) also recommend the use antiplatelet agent (Aspirin) at a dose of 75-100 mg/day along with anticoagulant to decrease the incidence of thromboembolic events after valve replacement surgery.[3,4] In consistency with the guidelines from our study it clear that majority of the patients were given with aspirin to prevent thromboembolic events associated with valve replacement.

CONCLUSION

From the present study it is evident that mitral valve is the most common valve which is getting affected in majority of the population from given sample size. The major reason or the valve pathology was found to be combination of both stenosis and regurgitation. Mechanical valve was used majorly for replacing the affected valve when compared to bioprosthetic valve. Post valve replacement patients are always at a higher risk of developing thromboembolic events hence antithrombotic therapy needs to

be administered in such patients. Anticoagulation with Acitrom along with an antiplatelet therapy (Aspirin) were considered in majority of the patients which may increase the risk of bleeding, hence regular INR monitoring needs to be practiced. Optimal INR range varied depending upon the type of valve replaced and also the type of valve affected. The use of anticoagulants varied based on per day INR value. Too much increase in value of INR i.e. beyond the range given by various guidelines, the anticoagulant drug may also be kept on hold.

As this study was a short duration study (6 months) follow up details for thromboembolic and bleeding events were not assessed, hence future research works can focus on incidence of thromboembolic events after valve surgery and bleeding events in patients after valve surgery administered with anticoagulants and antiplatelets.

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CONFLICT OF INTEREST

The authors declare that there is no conflict of interest.

ABBREVIATIONS

INR: International Normalized ratio; **LV:** Left Ventricle; **AVR:** Aortic Valve Replacement; **MVR:** Mitral Valve Replacement; **DVR:** Dual Valve Replacement; **AS:** Aortic Stenosis; **MS:** Mitral Stenosis; **AR:** Aortic Regurgitation; **MR:** Mitral Regurgitation; **VKA:** Vitamin K Antagonist; **ACC/AHA:** American College of Cardiology/American Heart Association; **SD:** Standard Deviation; **SOB:** Shortness of Breath; **n:** Number of participants; **ECHO:** Echocardiogram; **RHD:** Rheumatic Heart Disease.

ETHICAL APPROVAL AND CONSENT TO PARTICIPATE

The study protocol was reviewed and approved by the Institutional Ethics Committee of Geetanjali University, Udaipur, Rajasthan, India with approval reference number GU/HREC/EC/2023/2378. Written and verbal informed consent was obtained from all study participants prior to inclusion. The study was conducted in accordance with the ethical principles outlined in the Declaration of Helsinki.

SUMMARY

The present study identified the mitral valve as the most commonly affected valve, with combined stenosis and regurgitation being the predominant pathology. Mechanical valves were more frequently used for replacement than bioprosthetic valves. Due to the increased risk of thromboembolic events post-surgery, most patients received anticoagulant therapy (Acitrom) in combination with antiplatelet therapy (Aspirin). This dual therapy highlights the need for careful INR monitoring to minimize bleeding risks. INR values varied depending on the type of valve replaced, influencing the dosing and management of anticoagulation. In some cases, elevated INR levels led to temporary withholding of the anticoagulant.

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