



LOW-DOSE ANTICOAGULATION IN PATIENTS WITH MECHANICAL HEART VALVES – A RETROSPECTIVE STUDY

Cardiology

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ABSTRACT

The aim of this study is to study the efficacy of low dose anticoagulation in patients after mechanical heart valve replacement and maintaining INR near the lower limits of international standard.

Mechanical valves were implanted in 254 patients between 2012 and 2017 and followed up for 1 year and it was observed that low-dose anticoagulation (international normalized ratio 1.9–2.5) could markedly decrease bleeding and effectively decrease the incidence of thromboembolism.

AIM The aim of this study is to study the effect of low dose anticoagulation in patients after mechanical heart valve replacement. So as to Maintain INR near the lower limits of international Recommendation standard.

MATERIALS AND DESIGN

Place of study	Dept of cardiothoracic surgery, Stanley medical college, Chennai.
Sample size	254
Study design	Retrospective
Duration	2012 to 2017

Inclusion Criteria: All patients who underwent valve replacement surgery in department of CTS In Stanley medical college.

Exclusion Criteria

- Patients having liver function abnormalities
- Patients having CVA
- Patients who underwent double valve replacement
- Patients who underwent Bioprosthetic valve replacement

Methodology

- A Total of 254 consecutive patients undergoing valve replacement surgery at Stanley medical college are included in this retrospective
- ,randomized study.
- Inclusion and exclusion criterias applied
- Cases followed up retrospectively and INR values recorded every 3 months in tables.
- Bleeding and thromboembolic events and other complications if any were recorded.
- Statistical analysis used:SAS

KEYWORDS

MVR, AVR, INR.

INTRODUCTION

Due to differences in blood coagulation characteristics, patient compliance, demographics the standard INR formulated in guidelines may not be applicable to all population groups. The aim of this study was to provide observational guidelines for optimal and safe anticoagulation in patients after mechanical heart valve replacement.

PATIENTS AND METHODS

From 2012 to 2017, 254 patients who underwent valve replacement surgery with mechanical heart valve in Stanley medical college cardiothoracic surgery dept.

Follow-up in the outpatient clinic was routinely recorded for all patients. In those who were enrolled in this study, the data were collected.

Preoperative hepatic function, platelet count, and prothrombin time (PT) were normal. Operations were performed using cardiopulmonary bypass with moderate hypothermia and cold crystalloid cardioplegia. Intravenous administration of heparin was started at 0.5 mg/kg–1 every 4 to 6 hours for patients maintained on mechanical ventilation and Oral anticoagulation therapy was commenced with an initial dose 4 mg of Acitrom on the second postoperative evening. Dosage of Acitrom was titrated to achieve the target INR range was 1.9 to 2.4 for patients with aortic prostheses and 2.0 to 2.5 for those with mitral prostheses. All patients were required to present for outpatient department after hospital discharge monthly twice for followup and to collect drugs. Every 3 months once INR values were observed and recorded.

Variables	MVR	AVR
No. of patients	172	82
Etiology		
Rheumatic heart disease	158	77
Congenital valve prolapse	4	2
Regurgitation + infective endocarditis	6	2
Degeneration	4	1
AVR = Aortic Valve Replacement, MVR = Mitral Valve Replacement.		

All data were collected retrospectively. Valve-related complications and deaths were defined in compliance with the guidelines.

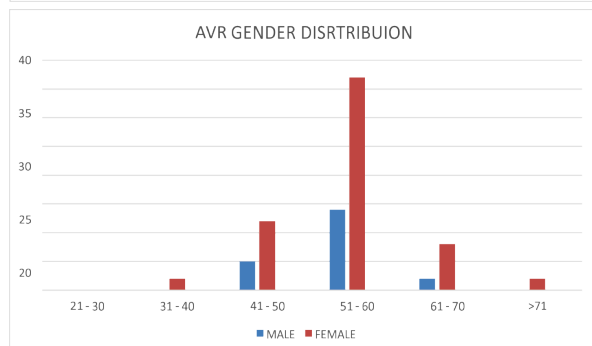
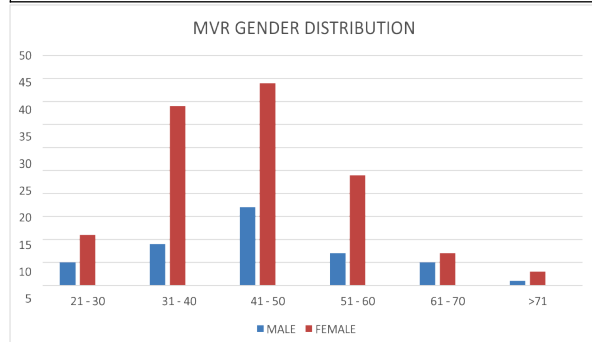
Table 2. Comparison of Bleeding & thromboembolic Events in Different INR Ranges.

Valves Replaced	INR Range	Thromboembolic Events (TIA, Stroke)	Bleeding Events
Aortic	1.9-2.4	1	0
	>2.4	0	5
Mitral	2.0-2.5	1	2
	>2.5	0	7
INR = International Normalized Ratio			

Table 3. Difference In Mean INR During 4 Postoperative Periods

Postoperative Period	Mean INR
Within 1 month	2.42± 0.27
1–3 months	2.15 ± 0.22*

3-6 months	2.34 ± 0.19*
6-12 months	2.05 ± 0.21*
*p < 0.05 vs. INR Values Within The First Month. INR = International Normalized Ratio.	



DISCUSSION

Patients who underwent mechanical heart valve replacements require life-long anticoagulation therapy. Anticoagulant-related bleeding is the major complication in those patients. The morbidity from bleeding is approximately 7% per patient year, which is far greater than that of thromboembolic events 1-2% per patient year. Anticoagulation therapy requires a precise marker for monitoring. Our unit adopted the INR as the monitoring marker. It is generally considered that the dose of anticoagulation should be controlled within an optimal range to minimize hemorrhagic complications. "In 2001, the American College of Chest Physicians advocated the implementation of low-intensity anticoagulation: INR 2.0-3.0 after AVR; 2.5-3.5 after MVR and DVR; and 2.5-3.5 for patients with a large left atrium or atrial fibrillation". The target INR range set in this study was based on past clinical experience. The incidence of bleeding within the target INR range (1.9-2.4 for AVR, 2.0-2.5 for MVR) was much less than when the target range was exceeded. The final INR in patients without bleeding was 1.88-2.40, which suggests that an INR of 1.9-2.5 is optimal for patients and this coincides with previous observations. Therefore, it is more important to focus on preventing the occurrence of bleeding in patients rather than the incidence of thromboembolic complications.

In south India, the monitoring of INR and subsequent Acitrom dosage adjustment after hospital discharge is a significant challenge due to geographical restrictions, economic conditions, and lack of medical knowledge. Whilst almost all the patients in this group complied with the study protocol, many south indian patients with a mechanical heart valve prosthesis are not able to return to hospital for regular follow-up. Thus, it is necessary to set an optimal regime which could make the anticoagulation more precise, and also decrease the cost and frequency of follow-up. "The fluctuation of INR in the first study month was greater than in other periods, demonstrating that the INR was most unstable in the immediate postoperative period". During this time, many factors such as hepatic function, platelet levels, and concomitant medication can influence the effect of anticoagulation. Therefore, follow-up in the first month after discharge from hospital is the most critical. We suggest that patients be seen at least twice in this defining month.

RESULTS

From our study, out of 172 MVR patients, 1 patient developed Transient ischemic attack and 2 patients developed bleeding complications with INR maintained between 2.0 to 2.5. 7 patients developed bleeding

complication, no one developed thromboembolic events with INR maintained more than 2.5.

Out of 82 AVR patients, 1 patient developed Transient ischemic attack and no patients developed bleeding complications with INR maintained between 1.9 to 2.4. 5 patients developed bleeding complications, no one developed thromboembolic events with INR maintained more than 2.4

CONCLUSION

The Data collected suggests lower dose of Anticoagulation and Maintain INR at lower limits of international recommendation standard doesn't increase the risk of Thrombo-embolic events in patients compared to conventional dose of anticoagulation management. In low dose of anticoagulation bleeding complications also lesser than the conventional dose of Anticoagulation management. A More Elaborate and Larger randomized controlled study is needed to further evaluate INR titration in future.

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