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FREQUENCY OF ACHIEVING TARGET INR IN PATIENTS WITH PROSTHETIC HEART VALVES

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ABSTRACT

Objective: To assess the frequency of achieving target International Normalization Ratio (INR)   in patients with mechanical prosthetic heart valves.

Methodology: It was a cross-sectional observational study, in which patients with mechanical prosthetic heart valves implanted at least a month ago, attending outpatient department of National Institute of Cardiovascular Disease from August 2010 to December 2010 were included. All patients were interviewed for their basic demographics, type of valve implanted and their INR in last six months.

Results: A total of 85 patients were enrolled with 51 (60%) females with mean age of 36 years and 34 (40%) males with mean age 40 years .Valve replaced was mitral in 68(80%), aortic in 10 (11.8%) and both mitral and aortic in 7 (8.2%) patients. The INR of only 27(31.85) patients were found within target, set according to recent guidelines, while 49(57.6%) were below and 09(10.6%) were above the target.

Conclusion: Majority of patients with prosthetic heart valves are under coagulated. New strategies are needed to address this important issue.

Key Words: Mechanical prosthetic valve, Target INR, Oral anticoagulation.

INTRODUCTION

Cardiac valve replacement is very frequently done in tertiary care cardiac centre all over the world. About 15 million people in United States suffer from either aortic or mitral valve disease.[1,2] In South Asian countries like Pakistan rheumatic heart disease is still major culprit in affecting heart valves at an early ages.[3] Its late recognition and improper prophylaxis leads to rapid structural deterioration of heart valves.[4] This makes patient a candidate for mechanical valve replacement at relatively early age.[5]

All patients with mechanical heart valves need oral anticoagulation with warfarin to keep international normalization ratio between 2-3 or 2.5-3.5 according to valve type, position and other comorbid conditions.[5-9] Although warfarin is very useful in reducing risk of thrombosis but increases risk of hemorrhage as well.[10-13] So considering previously mentioned facts patients with mechanical heart valves needs a very strict monitoring of their warfarin treatment to keep their INR in recommended ranges for prevention of over or under coagulation.

Studies done in Pakistan described frequency of target INR achievement in broad range of patients on long term anticoagulation but not specifically for mechanical heart valves which is the most high risk indication for oral anticoagulation.[14,15] It is important to know the frequency of achieving target INR in our patients with mechanical prosthetic valves on oral anticoagulation.

The aim of our study was to assess the frequency of achieving target INR in patients with mechanical prosthetic heart valves.

METHODOLOGY

After approval from ethical review committee patients in this cross-sectional study were enrolled from August 2010 to December 2010 at outpatient department of National Institute of Cardiovascular Diseases. Subject included were with mechanical prosthetic heart valves implantation at least a month ago, excluding those with known ischemic heart disease and pregnancy.

After an informed consent subjects were interviewed with a structured questionnaire evaluating their basic demographics, education, economic status, date of surgery, type and position of valve implantation, associated risk factors of thromboembolism and their understating of target INR for them. Record of INR done in last six months and comprehensive drug history of warfarin and other medication taken in last month was also evaluated. Target INR means target set for that patient according to AHA recommendations[5] considering site, type of valve and thromboembolic events.

Statistical analysis was performed using statistical package for social sciences (SPSS) version 13. Numerical variables were presented as mean ± SD. Categorical variables were presented as frequencies and percentages.

RESULTS

A total of 85 patients were evaluated with 12-78 years of age for males and 13-68 years for females with further demographic variables described in Table 1. Valve replaced was mitral in 68 (80%), aortic in 10 (11.8%) and both aortic and mitral in 7 (8.2%). Warfarin as a single anticoagulant was used in almost all patients with occasional addition of antiplatelet like aspirin and clopidogrel, details of which are given in Table 2. The International Normalization Ratio (INR) of only 27 (31.8%) was found within target considering recent guidelines and patient characteristics while 49 (57.6%) were below and 09 (10.5%) were above target, details of different levels of INR in both sexes are given in Table 3.

Table 1: Demographic Variables

Variable	Total	Male n (%)	Female n (%)
No of patients	85	34 (40)	51 (60)
Age (mean)		40.32	35.66
Married	62 (72)	25 (73)	37 (72.5)
Diabetic	02 (0.2)	01 (3)	01 (2)
Hypertensive	06 (0.7)	02 (6)	04 (9)
Past CVA/TIA	23 (27)	07 (20.5)	16 (31.3)

Table 2: Weekly Warfarin Dose

Weekly Warfarin Dose	Total Number of Patient	Male	Female
17.5 mg	12	4	8
22.5 mg	4	3	1
35 mg	57	21	36
52.50 mg	10	4	6
70 mg	2	2	0

Table 3: Gender wise Details of Achieved INR

Variable	Total, n = 85 (%)	Male, n (%)	Female, n (%)
INR 1-2	26 (30.5)	13 (50%)	13 (50%)
INR 2-3	43 (50.5)	16 (37%)	27 (63%)
INR 3-4	16 (19)	05 (31%)	11 (79%)
INR within target	27 (31.7)	10 (37%)	17 (63%)

DISCUSSION

About 15 million people in United States suffer from either aortic or mitral valve disease. More than 60,000 cardiac valve replacement procedures are performed annually in the United States. In South Asian countries like Pakistan rheumatic heart disease is still major culprit in affecting heart valves at an early age.[3]

All patients with mechanical heart valves need oral anticoagulation with warfarin according to valve type, position and other comorbid. Various studies have shown that significant number of patients remain outside of the recommended INR level. Our study demonstrated a relatively low, 31.8% of our patients with prosthetic mechanical valves receiving appropriate oral anticoagulation on outpatient basis, in spite of a regular follow up to a tertiary care centre. In recent study researchers found at any given time 21.8% to 32.5% of patients were outside the target INR set for them.[15] Other authors have found an even greater number of patients (up to 52%) outside the target INR range.[16]

Our study also demonstrated that a very low percentage of patients were on regular aspirin, which is now class I indication for all mechanical valves.[17] These results were similar to a study done by Ahmed et al, on efficiency of oral anticoagulation.[16] Although this fact is very much evident in the literature that no matter how you manage oral anticoagulation a significant number of patients remain outside of the recommended INR level.[18] Application of various strategies like self management anticoagulation clinics or community physicians yielded a result of around 60-70% of patients in target range.[19-21] Since our patients were specifically of prosthetic mechanical valves, most high risk for thromboembolic events with variably high targets, which is difficult to achieve.[15,22,23]

Majority of our patients were having adequate frequency of testing. Only some of our patients had infrequent testing. The optimal frequency of long-term INR monitoring is influenced by patient compliance, transient fluctuations in comorbid conditions, the addition or discontinuation of other medications, changes in diet, the quality of dose adjustment Decisions, and whether the patient has demonstrated a stable dose response. Some clinical trials[15,24] have suggested that during long-term treatment fewer adverse events can be maximized by more frequent testing.

Computerized dose management (with specific software programs) is another option that has been shown to be at least equivalent to physician-managed dosing when large populations of patients are being managed. Clinical benefit from the use of computer programs over conventional medical staff (manual) dosing has, however, not yet been established.

Our study was done in patients who were attending outpatient department of a tertiary care centre so these

results can't be translate to whole community where target INR achievement may still be less.

CONCLUSION

A vast majority of patients with mechanical prosthetic heart valves are under coagulated and very few of them were on low dose aspirin. A comprehensive management training of hospital staff and dedicated anticoagulation clinics are needed to make our results comparable to international standards.

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