

A Study to Assess the Knowledge Compliance and Complications of long-term oral Anticoagulation Therapy among patients following mechanical valve replacement in the Madras Medical Mission Hospital, Chennai.

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ABSTRACT:

INTRODUCTION:A descriptive correlational study was conducted to assess the knowledge compliance and complications of long term oral anticoagulation therapy among patient following mechanical valve replacement in the MMM Hospital, Chennai. **OBJECTIVES:**1. To assess the knowledge regarding anticoagulant therapy. 2.To assess the compliance to long term oral anticoagulant therapy among valve replacement patients.3. To assess the complication encountered due to long term anticoagulation therapy among valve replacement patients. 4.To correlate the knowledge and compliance of long term oral anticoagulation therapy.5. To correlate the compliance and complication of long term oral anticoagulation therapy.6. To associate the knowledge, compliance and complications to selected demographic variables.**CONCEPTUAL FRAMEWORK:**Modified conceptual framework of Health belief model of Rosenstock 1974 and Becker 1975. **RESEARCH DESIGN:** Quantitative, descriptive correlational research design. **SETTING:** Cardiothoracic outpatient department of The MMM Hospital, Chennai. **SAMPLES:**100 subjects were selected who fulfilled the criteria.**SAMPLING TECHNIQUES:**Non probabilitypurposive sampling technique.**METHODS:** Semi structure interview questionnaires were used to assess demographic & clinical variables and knowledge level, compliance, complications of patients about oral anticoagulant drug therapy. Data was collected from 3/2/2021 – 3/3/2021. Outcomes were evaluated by descriptive and inferential statistics. **RESULTS:** The finding revealed that 69% patients had adequate knowledge, 29% patients had moderate knowledge and 2% patients had poor knowledge. The mean score was 18.41 with a SD of 2.94. 100% patients had good compliance the

mean score was 19.01 with a SD of 1.34. 94% patients had mild complication, 5% had moderate complication, 1% patient had severe complication. There was moderate positive correlation r value of 0.306. between knowledge and compliance. There was moderate negative correlation r value of - 0.129. There was association between knowledge and selected demographic variables such as education, occupation and history of valve replacement. There was association between complications and selected demographic variables such as age and physical activity. **CONCLUSION:** The findings of the study revealed that patients had adequate knowledge and good compliance about long term oral anticoagulant drug therapy and patients had mild complication of anticoagulant drug therapy.

KEYWORDS:Knowledge, Compliance, Complication, Mechanical Heart Valve Replacement, Oral Anticoagulation Therapy

INTRODUCTION:

“Our hearts are the core of whom we are, with in their deeper essence are to be found all those qualities. That makes us to feel fully alive and connect us to our profounder humanity”.

Dr. Serge

Beddington

A tissue valve replacement surgery the badly damaged valve is replaced in human hearts. These are chemically treated for safety and are specially prepared for the human since they are weak; they are reinforced and supported with a frame or stent to make the valve stronger. When the valves aren't reinforced, they are known as stent less valves¹⁸. Mechanical valves are made to last lifelong for all patients. They do not wear out or break down; its durability is tested using mechanical wear analysis. They offer a competitive

hemodynamic performance. Mechanical valves allow patients to continue the same level activity throughout their lifetime¹⁹. Mechanical heart valve patients are more likely to develop blood clots in the heart when compared to bio prosthetic heart valve. The blood clots may break loose, travel to the brain and cause stroke. A patient who receives a mechanical heart valve to treat severe valvular heart disease, needs to take anticoagulants for life time in order to prevent clot formation¹. The common side effect of warfarin is hemorrhage; other complications are hypersensitivity or allergic reactions like urticaria and anaphylactic reactions, vasculitis, nausea, vomiting, diarrhea, taste perversion, abdominal pain, flatulence, bloating, rash dermatitis, pruritis, alopecia, tracheobronchial calcification, hepatitis and elevated liver enzymes. Cholestatic hepatitis was associated with administration of warfarin sodium and ticlopidine¹³.

BACKGROUND OF THE STUDY

Degenerative valve disease is a growing concern due to the rising amount of valve replacement surgeries among the elderly. More than 300,000 prosthetic heart valve surgeries were performed each year worldwide, and this rate is projected to increase to as many as 850,000 per year by 2050. There is a high risk of thromboembolic events following heart valve surgery; to which anticoagulation and antiplatelet therapies are necessary. The drug selection depends on the type of surgery performed and the individual risk in any given situation¹¹. (Benesov, M. 2011). Warfarin is the most commonly prescribed oral anticoagulant therapy in the United States. It is effective for the prevention and treatment of thromboembolism in the setting of prosthetic heart valves, atrial fibrillation, and myocardial infarction. As there was increase in the aging of United States population, the number of patients treated with warfarin continued to increase. In 2004 alone, the number of outpatient prescriptions for warfarin was around 31 million. Approximately 4 million outpatients in the United States and 7 million patients worldwide are receiving long-term oral anticoagulant therapy, using warfarin or coumadin¹⁷. (Edith A., et al 2011)

NEED FOR THE STUDY

Anticoagulant management should encompass the effective management of risk factors for thromboembolism in addition to the prescription of anticoagulant drugs. Lifelong oral anticoagulation is recommended for all patients

with mechanical valve irrespective of valve type or date of introduction. Having experience in postoperative cardio thoracic wounds and caring patients with valve replacement. With the growing consumer awareness and internet access to individuals, are patients aware about the medication. The investigator always felt that understanding the knowledge and compliance to medication is vital in providing appropriate nursing health education.

MATERIALS AND METHODS

RESEARCH SETTING

The study was conducted in the cardiac outpatient's department of The Madras Medical Mission Hospital, Chennai.

POPULATION

The population comprised of follow up patients with prosthetic mechanical heart valve on anticoagulant drug therapy during the study period.

SAMPLE

Long term oral anticoagulation therapy patients following mechanical heart valve replacement in The MMM Hospital, Chennai.

SAMPLE SIZE

It was decided to select 100 sample for this study.

SAMPLING TECHNIQUE

Non probability purposive sampling techniques was adopted for the study.

Inclusion criteria

- Were the patients age >18 years who underwent mechanical valve replacement and receiving warfarin.
- The patients who have more than 6 months after valve replacement procedure.
- Patients after valve replacement willing to participate in the study.
- Patient who can understand and communicate in Tamil (or) English.

Exclusion criteria

- Platelet counts < 100,000/mm³ during bleeding events.
- Thromboembolic events heparin induced thrombocytopenia, myeloproliferative disorder, hyper viscosity syndrome.
- Did not have follow up data more than 2 year
- Those are taken other drug like antineoplastic drugs, carbamazepine
- Patient with severe renal failure severe postoperative complication & poor prognosis.

DESCRIPTION OF THE TOOL

The data collection tool consisted of three sections.

Section A: Demographic data

It comprised of demographic variables of the subjects which includes age, sex, education, occupation, family income, physical activity level.

Section B: Clinical variables

It comprised of clinical variables of the subjects which includes comorbid conditions, history of valve replacement surgery, present medications, previous history of cardiac surgery, last INR value.

Section C: Semi structured interview questionnaires

The tool was prepared following extensive review of literature and discussion with experts. The knowledge questionnaires 12 multiple response question to assess the knowledge. In order to assess the compliance 3-point rating scale (Always- 2, Sometimes-1, Never-0) was prepared it consisted of 10 items. The complications were assessed using the checklist (Yes-1, No-0) type it consisted of 10 items.

VALIDITY

The tool was submitted for content validity to experts in the field of cardio thoracic surgery and medical surgical nursing in and around Chennai. The translated Tamil version of the tool was validated by Tamil experts. Based on their suggestions and recommendations, the tool was finalized.

RELIABILITY

Reliability of the tool is a degree of consistency with instruments, measures the attribute it is designed to measure.

The reliability of the tool was determined using the Spearman Brown's Split Half technique which showed $r = 0.92$ for semi structured questionnaires, Hence the tool was found highly reliable.

DATA COLLECTION PROCEDURE

The data collection period was one month. Data was collected every day from 3/2/2021 – 3/3/2021. The samples selected were given a self-introduction and then an oral and written consent was obtained from them. The participants were assured about confidentiality of the data collected and told that it will be used only for research purpose. The knowledge, compliance and complication questionnaire and demographic, clinical data were administered on the patients who have more than 6 months after valve replacement procedure. The patients took approximately 10 min. to complete the tool. The investigator was present

throughout the data collection period to clarify any doubts expressed by patients.

RESULT

DISTRIBUTION OF PATIENTS BASED ON LEVEL OF KNOWLEDGE, COMPLIANCE AND COMPLICATIONS OF ANTICOAGULATION THERAPY

In the present study finding that in 69 (69%) patients had adequate knowledge, 29 (29%) patients had moderate knowledge, 2 (2%) patients had poor knowledge. The mean score was 18.41 with a SD of 2 .95. All 100 (100%) patients had good compliance. The mean score was 19.01 with a SD of 1.34. Majority of the patients 94 (94%) had mild complication, 5 (5%) patients had moderate complication and 1 (1%) patient had severe complication. The mean score was 0.9% with a SD of 1.34.

CORRELATION BETWEEN KNOWLEDGE, COMPLIANCE AND COMPLICATIONS OF LONG TERM ORAL ANTICOAGULATION THERAPY

The study findings showed moderate positive correlation between knowledge and compliance. The correlation score was $r = 0.306$. As the knowledge increased compliance is also increased. Moderate negative correlation between compliance and complications. The correlation score was $r = -0.129$. As the compliance increased there was a decrease in complications.

ASSOCIATION BETWEEN KNOWLEDGE, COMPLIANCE AND COMPLICATIONS TO SELECTED DEMOGRAPHIC VARIABLES

The study findings showed that association of knowledge with demographic variables among patients with mechanical valve depicts the significance of association of knowledge with demographic variables. It shows that the calculated chi square value of education is 9.771 at $df = 6$, $p = 0.032$ and occupation prescribed is 10.823 at $df = 6$, $p = 0.041$ and history of valve replacement prescribed is 5.857 at $df = 6$, $p = 0.047$ significant at 0.05 level of significance. There is no association between the knowledge and other demographic variables such as age, sex, physical activity, family income and last INR value.

DISCUSSION

Sara., et al (2011) conducted a cross – sectional study on 57 patients. To determine the patient's knowledge and adherence to oral anticoagulant drug therapy after mechanical valve replacement surgery, for patients with congenital or

acquired valve defects. Patients' knowledge was measured using the oral anticoagulation tool. A visual analogue scale was used to assess the adherence to therapy. Results revealed that most of the patients had lack of knowledge on oral anticoagulants, three – quarters of patients were 100% adherent to oral anticoagulant therapy, and about one fourth of the patients did not fully adhere to therapy.

The finding of the present study are in agreement with above cited studies which shows that 69% patients prescribed with anticoagulant drug have adequate knowledge and 29% patients had moderate knowledge and 2% patients had poor knowledge.

Khudair. (2010) conducted a cross sectional study in the outpatient anticoagulation clinic to evaluate the patient's knowledge on warfarin compliance, in a teaching hospital in Qatar. Self-administered questionnaire was offered to patients taking warfarin at least 2 months in patients who were attending the cardiology or medical anticoagulation clinics in General Hospital Hamad. Results showed that an integrated and multidisciplinary education program can improve the patient's knowledge on warfarin and its compliance.

The findings of the present study are in agreement with above cited studies which shows that patients have adequate compliance about long term oral anticoagulant drug therapy.

Anna., and Robert. (2013) conducted a prospective study. Patients after aortic or mitral mechanical valve replacement were selected, to evaluate the pharmacokinetics and safety of oral dabigatran and etexilate. Patients were selected and assigned to receive warfarin or dabigatran in 2:1 ratio with dabigatran renal dose at 150 to 300 mg twice daily in order to achieve plasma through of at least 50 mg per milliliter, to prevent valve thrombosis. Warfarin was dosed to achieve international normalized ratio 2.0-3.0 or 2.5 -3.5, depending on patients' thromboembolic risk. Study that comparing to warfarin, dabigatran had an increased risk of thromboembolic events and bleeding in patients with mechanical heart valves.

The finding of the present study are in agreement with above cited studies which shows that patients have mild complications of long term oral anticoagulation therapy.

Zahid., et al (2020) conducted a cross sectional study in Karachi, Pakistan. To assess the knowledge of oral anticoagulant therapy and its side effects its users. Face -to-face interviews were

conducted among 230 samples with using anticoagulation knowledge tool. The majority of patients (65.7%) did not know what side effects to be wary of or how to reduce their occurrence, most of them were unaware of the interaction between oral anticoagulant drugs and over- the- counter substances such as aspirin, herbal medicines and alcohol. Knowledge of INR was extremely poor with more than 75% of the population not being aware of the target INR range during warfarin therapy. Higher level of education was significantly associated with better knowledge scores. Knowledge of oral anticoagulant therapy and INR monitoring is extremely poor among oral anticoagulant users.

The findings of the present study are in agreement with above cited studies which shows that there is a mild association between the knowledge and demographic variables and there is a mild association between complications and demographic variables.

NURSING IMPLICATIONS

The findings of the study has implications of various areas of nursing practice, nursing education, nursing administration and nursing research.

Nursing Practice

The role of nurse in patient education cannot be overlooked (**Monsivais & Reynolds, 2003**)

- The nurse plays an important role in disease prevention & health promotion education program with effective strategies, which motivate the people to follow healthy practices in day to day life. Step should be taken to educate the patients to make them aware about anticoagulant drug knowledge and compliance and complications Information education communication booklet once developed and distributed to all follow up mechanical heart valve replacement patients.
- Nurses can help saving the lives of many by teaching and creating awareness on anticoagulant drug therapy among patients with mechanical heart valve replacement.
- Nurses can develop Information Education Booklet on importance of OAT, guidelines for taking medications and life style modifications. The same can be distributed to patients on discharge.
- Nurses should translate the evidences available on knowledge, compliance and complications regarding anticoagulant drug in regular routine practices.

Nursing Education

Finding of the present study have an implication of nursing education.

- The curriculum should stress the importance of anticoagulants, guidelines for while taking medication, and first aid techniques for minor bleeding for patients with mechanical heart valve
- The nurse educator must be able to assess the student nurse's knowledge regarding anticoagulant drug compliance and complications
- The nurse educator should arrange continuing nursing education for staff nurses in order to updating their knowledge on anticoagulant drugs and its compliance and complications.

Nursing Administration

The findings of the study will help nurse administrators to organize and plan for various programs to provide information to provide immediate teaching for patients about awareness on anticoagulant drugs after mechanical heart valve replacement surgery

- Nurse administrator can plan in service education / continuing nursing education programs regarding anticoagulant drugs and its compliance, importance and complications for mechanical heart valve replacement patients.
- The nurse administrators should take initiative to display health education materials / posters in OPD and post-operative wards regarding oral anticoagulant therapy.
- Arrangement of an exclusive nurse specialist who can collaborate with the multidisciplinary team, in order to support and educate awareness of anticoagulant on mechanical heart valve replacement patients.

NURSING RESEARCH

- The present study is an attempt to assess the knowledge compliance and complications of long term oral anticoagulant drug therapy among patients with mechanical heart valve.
- Nursing research on importance of anticoagulant drug therapy will be a valuable reference material for further researchers.
- Qualitative research can be undertaken to assess the self report of the participants.

CONFLICT OF THE STUDY

The authors have no conflicts of interest regarding this investigation.

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