



SCHOOL OF NURSING

ADHERENCE TO ANTICOAGULANT MEDICATION AND ITS ASSOCIATED FACTORS AMONG CHILDREN WITH CARDIAC PROBLEMS ATTENDING CARDIAC OUT PATIENT DEPARTMENT AT PUBLIC HOSPITALS ADDIS ABABA, ETHIOPIA, 2024

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A THESIS PAPER TO BE SUBMITTED TO St. PAUL'S HOSPITAL
MILLENNIUM MEDICAL COLLEGE SCHOOL OF NURSING,
DEPARTMENT OF ADULT HEALTH NURSING IN PARTIAL
FULFILLMENT OF MASTERS DEGREE IN CARDIOVASCULAR
NURSING

February, 2024

Addis Ababa, Ethiopia

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ABSTRACT

Introduction: A patient's ability to take prescription medications as advised and their continuous use of those medications are referred to as medication adherence. Children often have difficult times adhering to their medication regimens, which can result in a bad prognosis and hospital stays. Fifty percent of treatment failures and deaths can be attributed to non-adherence. Given the lack of research in this field, this study will close the knowledge gap by estimating the prevalence of anticoagulant medication non-adherence in children and its contributing factors, Addis Ababa, Ethiopia.

Objective: To assess the adherence of anticoagulant medication and its associated factors among children with cardiac problems attending cardiac OPD of Selected Public Hospitals, Addis Ababa, Ethiopia, 2024

Methods and material: An institutional based cross-sectional study design was used from March 1, 2024 –April 1, 2024 on children with cardiac problems attending there follow up at Cardiac Center Ethiopia, St. Paul's Hospital and St. Peter's Hospital. The questionnaire was pre-tested in children from other hospital then the data was interred in SPSS for Cronbach's alpha reliability test with a cut of point being 70 and above was 72. Survey method was used in which all children at the time of data collection were taken. Association between dependent and independent variables was assessed multivariate analysis P-value < 0.05 was taken as statistically significant and to control confounders. Adjusted odds ratio (AOR) was calculated to determine the association between the dependent and independent variables at 95% confidence interval (CI).

Result: There were 192 participants in this study among them 14.6% have poor adherence to anticoagulant therapy. Duration of therapy (AOR: 0.118, 95% CI: 0.034-0.410) and awareness of their medical condition (AOR: 0.043, 95% CI: 0.011-0.165) have significant association with anticoagulant adherence.

Conclusion and Recommendation: Among the children with cardiac problems on follow up at cardiac OPD of selected public hospitals in Addis Ababa 14.6% were not

adherent to the anticoagulant medication they were taking. Early identification of the problem, counseling, follow up, psychosocial support to the children as well to the caregiver helps with preventing the complication that comes with non-adherence.

Keyword: anticoagulants, adherence, Children, cardiac problems

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ACRONYMS / ABBRIVATIONS

- AYA – Adolescents and Young Adults
- ACCP – American College of Chest Physicians
- ADE – Adverse Drug Events
- AIS – Arterial Ischemic Stroke
- BID – Two Times a Day
- BVTR – Between Visit Time in Therapeutic INR Range
- CVD- Cardio Vascular Disease
- CHD – Congenital Heart Disease
- CAD – Coronary Artery disease
- CCE – Cardiac Center Ethiopia
- DOAC – Direct Oral Anticoagulant
- DTI – Direct Thrombin Inhibitor
- INR – International Normalized Ratio
- LMWH – Low Molecular Weight Heparin
- NOAC – New Oral Anticoagulants
- OAC – Oral Anticoagulants
- OPD - Out Patient Department
- QD – Once a Day
- PE – Perinatal Embolism
- PTS – Post-Thrombotic Syndrome
- SPHMMC – St. Paul’s Hospital Millennium Medical College
- SPSH – St. Peter Specialized Hospital
- UFH – Unfractionated Heparin
- VTE – Venous Thromboembolism
- WHO – World Health Organization

CHAPTER ONE

INTRODUCTION

1.1 Background

The World Health Organization defines medication adherence as "the degree to which a person behaves in accordance with the agreed recommendations of a healthcare professional." A major health problem in the world is the lack of adherence to the patient's medication (1)(2). In spite of the fact that the phenomenon of persistent non-adherence is known since Hippocrates, it was in 1979 that this issue entered the medical writing, at first under the term "non-compliance", characterized as the inconsistency between patients' behavior and medical prescriptions(3).

Cardiovascular illnesses are the driving cause of death around the world, taking an evaluated 17.9 million lives each year. More than four out of five cardiovascular disease (CVD) deaths are due to cardiac attacks and strokes(4). Congenital heart disease (CHD) is characterized as a structural anomaly of the heart and great vessels that's present at birth. In spite of the fact that various etiologic examinations have been conducted, as it were roughly 15% of cases of CHD can be inferable to a known cause.(5)

There is broad agreement that individuals with CVD have a propensity to develop fibrin clots that are more rigid, have tightly packed fibers, and are more resistant to fibrinolysis. Pharmacological therapies used for both the treatment and prophylaxis of thromboembolic disease result in changes in fibrin clot structure and function (6).After cardiac procedures, children with cardiac issue especially those with cyanotic congestive heart disease run the risk of experiencing an arterial ischemic stroke. In children with heart disease, the causes of stroke are complex and include irregular flow, polycythemia, persistent hypoxia, embolic or thrombotic disease, and foreign objects or materials (7).

Anticoagulants are small molecules designed to selectively inhibit specific clotting factors in the human body's clotting pathway. (8). Direct thrombin inhibitors (DTIs),

fondaparinux, warfarin, low molecular weight heparin (LMWH), unfractionated heparin (UFH), and direct oral anticoagulants (DOACs) are examples of anticoagulants (9).

The most traditional and widely used oral anticoagulant (OAC) for the prevention of thromboembolic events is warfarin. The impact of multiple patient characteristics, such as medication non-adherence, on reaching and sustaining a therapeutic level makes proper dosing difficult even with substantial clinical experience with this medication(10)(11).Children taking warfarin medication may have chronic side effects that last a lifetime. Encouraging patients and their family to take care of their own warfarin leads to better patient self-management, adherence to prescription regimens, and increased knowledge and comprehension of their health condition(12)

Nearly 90% of doctors said they occasionally worried about their patients' non-adherence. Medication non-adherence is seen by clinicians who prescribe anticoagulation for children, adolescents, and young adults as a clinically serious problem that can lead to recurrent thrombosis or bleeding. Physicians believe that patients who miss doses and disregard monitoring advice are the most common causes of non-adherence(13).

A visual analogue scale and changes in adherence using a 7-day pill recall were found to be independently associated with anticoagulation control in a prospective study conducted in three urban anticoagulant clinics in Pennsylvania. The patient self-reported adherence using these two quick and easy tools for the assessment of adherence at each patient visit.(11)

1.2 Statement of the problem

Medication adherence often refers to a patient's ability to take prescription drugs as directed and their continued use of those drugs. There is much to learn about anticoagulant medication adherence in pediatric and adolescents and young adults (AYA) populations, even while non-adherence to anticoagulation in adults has been associated with higher morbidity and mortality(14).

Eighty-seven (43.5%) participants in an international survey on anticoagulant adherence in children, adolescents, and young adults reported caring for pediatric patients whose non-adherence resulted in new or recurrent thrombosis, and 36 (18.0%) reported experiences with non-adherence leading to bleeding. Furthermore, because of concerns about adherence, 75% of clinicians (n = 148) "sometimes" or more regularly modified prescriptions. An evaluated 3%–42% of children and young people endorsed anticoagulants illustrate pharmaceutical non-adherence(13).

Venous thromboembolism (VTE) in children, adolescents, and young adults (AYAs) ordinarily develops within the setting of different thrombotic risk factors. Of the 161 participants in the trial, this was done at Ohio State and Southeast Virginia Children's Hospital. The adherence to oral anticoagulants was reported by 79 patients (85% of patients) and 32 caregivers (47% of caregivers). The remaining participants (n = 14 [15%] patients, n = 36 [53%] caregivers) reported on the adherence to injectable anticoagulants.(14) Prevention of thromboembolism events in children with cardiac disease remains a significant concern to cardiologists and pediatric specialists. This is complicated by the fact that thrombotic rates in this population are not well characterized(15).

The withdrawal of anticoagulants is linked to an increases risk of myocardial infarction stroke and mortality. The most frequent result of non-adherence is thromboembolism, which can cause other problems including pulmonary embolism, which is extremely deadly and results in reduced or stopped blood supply to the lung (16).

Medication non-adherence has negative impacts not only on patients as well as physicians, healthcare providers and even medical researchers who are trying to

determine the medication's value for the target population. Medication non-adherence is a significant public health concern because of the possible impact it may have on the health care delivery(1).

Many obstacles prevent children and adolescents and young adults (AYAs) from adhering to their anticoagulant regimens. The most commonly mentioned obstacles for patients taking oral anticoagulants were forgetting to take the prescription, adverse drug reactions, and the need for a lifestyle change. The most frequent obstacles for patients administered injectable anticoagulants were pain, side effects from the medicine, and the need to change their lifestyle in order to take it(14). Due to its effects on sickness outcomes, quality of life, and financial burden on families and the healthcare system, medication non-adherence has been identified as a major problem among patients(17).

Adherence to anticoagulants guarantees both medication safety and successful stroke prevention. Increased mortality and morbidity from cardiovascular diseases are linked to poor adherence. It will be possible to identify the people at risk for non-adherence and devise effective interventions to increase medicine adherence by understanding the factors that influence anticoagulant adherence.(18)

Concerning children's non-adherence to anticoagulant treatment, no particular interventions are carried out. However an investigation of medication adherence issues in general was attempted. Reliable supply networks, reasonable costs, and universal and sustainable finance are necessary to get high rates of therapy adherence. The WHO's partners are working hard to increase access to medications worldwide. Social support has frequently been mentioned as significant aspect influencing how non-adherence affects health(19). To obtain social assistance, patients might join various kinds of groups, such as health maintenance organizations (HMOs) in the US. The WHO, health ministries, and development agencies play a significant role in supporting and directing community-based initiatives to address the social and economic factors influencing treatment adherence. These initiatives also aim to enhance the delivery of healthcare by teaching healthcare providers how to identify and assess non-adherence as well as how to predict it. A constant effort is undertaken to enhance patient information delivery through motivations that promote long-term, high adherence(20).

Medication adherence of these children is very challenging which can lead to poor prognosis and hospitalization. In Ethiopia there is very little known about anticoagulant adherence in pediatrics this may be due to difficulty of data collection and it seemed to be a neglected public health problem.

1.3 SIGNIFICANCE OF THE STUDY

Understanding the level of adherence to anticoagulant pose significant contribution to different stockholders in terms of improving the outcomes and quality of life of these children and parents as well. On the other hand inadequate adherence to anticoagulant therapy can lead to pharmaceutical side effects, disease progression, diminished functional abilities and a reduced quality of life. Therefore we must first determine the extent of anticoagulant medication adherence and non- adherence before we can begin to treat the issues of non- adherence. The lack of adherence to anticoagulant therapy among children with heart problems will be addressed by this study.

The clinical consequences of non-adherence in this population can be avoided, and the burden of treating the complications resulting from not taking these medications as prescribed can be reduced, by addressing the non-adherence factors and removing barriers that lead to poor anticoagulant adherence. It will also reduce the cost of the healthcare system and the use of medical resources such as hospital admissions and visits.

Additionally, the study will be crucial in informing medical professionals about the seriousness of the problem and increasing awareness among study participants' caregivers. It is expected that by broadening the scope and making it a resource, more scholars will get interested in the work and conduct more research.

CHAPTER TWO

2. LITERATURE REVIEW

2.1 Overview of medication adherence

In order to achieve clinical goals, medication adherence is a crucial part of patient care. In a 2003 report on drug adherence, the World Health Organization (WHO) states that "improving the effectiveness of adherence interventions may have a far greater impact on the health of the population than any improvement in specific medical treatment."

Opposition: Poor clinical outcomes, increased rates of morbidity and mortality, and unnecessary medical costs are the results of non-adherence.(21).

Clinical research shows that there are several effective long-term illness treatments available. However, in actuality, these explanatory studies' findings sometimes fall short of predictions, and treatment noncompliance is considered to be a major contributing factor. In developed nations, patients with chronic illnesses are estimated to take their medications just 50% of the time; in developing countries, this percentage is probably much higher.(19).

2.2 Level of adherence among children

A study conducted in Pennsylvania using 7-day pill recall with 3204 (median 4) visits discovered that 598 individuals' between-visit time in the therapeutic INR range was 36.8%. In 182 (5.7%) visits, participants reported < 80% adherence, whereas in 377 (11.8%) visits, they reported one missed pill in the previous seven days. Multivariable regression analysis with a visual analogue scale of $\leq 80\%$ and self-reported reduction in adherence since last visit (<36.8%) revealed poorer treatment of anticoagulation.(11)

A study at the Faculty of Medicine, Ramathibodi Hospital, Mahidol University, Bangkok, Thailand, found that, according to the pill count technique, 158 patients (75.24%) had good adherence to medical therapy, whereas 52 patients (24.76%) had poor adherence.(22)

According to a study, low adherence is likely a major contributing factor to insufficient anticoagulation management even in patients getting treatment in specialized

anticoagulation clinics where adherence is routinely emphasized. There was a two-fold increase in the probability of subtherapeutic anticoagulation for every one to two missed doses per week (20% to 30% of missing doses). This effect, which was independent of the other characteristics that were looked at and may alter INR, was associated with insufficient anticoagulation management during both the initiation and maintenance phases of therapy. Even small reductions in the INR below therapeutic levels are associated with a significant risk of thromboembolism and can lead to more frequent visits, dose modifications, and dosing errors. (10).

In a Cincinnati, Ohio study on pediatric medication adherence barriers, patients and caregivers reported an average of 1.85 hurdles and that they or their child took 96% of the recommended amounts. A significant linear relationship was observed ($p = 0.02$). After adjusting for drug type ($p = 0.06$), there was a significant correlation between a higher number of barriers and lower adherence ($p = 0.01$). For every unit increase in total obstacles (one additional barrier identified), adherence fell by 26%(23).

2.3 Associated factors of anticoagulant adherence

Age

According to a San Francisco, California study, children's daily controller-medication obligation increased as they grew older. By the time they were 7, children were responsible for over 20% of the daily controller-medication, ~50% by the age of 11, 75% by the age of 15, and 100% by the age of 19. While age and parents' race/ethnicity were shown to be significantly connected with daily controller-medication adherence in multivariate models, age and male gender were found to be strongly correlated with daily controller-medication responsibility in children. In a multivariate model with child gender, years following diagnosis, and parent education, only the variables of kid age ($P.001$) and male gender ($P.001$) remained significant.(24).

In a study carried out at the University of Texas in Austin, logistic regression demonstrated that, once other factors were taken into account, getting older was

substantially correlated with anticoagulant medication adherence (odds ratio = 1.5, 95% confidence range = 1.13-1.85).(25)

Burden of medication cost and duration of therapy

High costs for prescription drugs contribute to low medication adherence, which has a negative downstream effect on health care costs and outcomes. When compared to adherence among parents whose children started a low-cost long-term medication, parents whose children started a high-cost long-term medication were associated with an immediate 1.9% (95% CI, -3.8% to -0.9%) reduction and sustained absolute reduction in adherence, according to a cohort study conducted in the national US health insurer database using interrupted time-series analyses. Similarly, starting a chronic, expensive medication was linked to 4.8% (95% CI, -8.6% to -1.0%) reduced odds of optimal adherence, and those odds persisted throughout the follow-up period. The start of an expensive drug was linked to a smaller immediate 0.6% (95% CI, -1.3% to -0.01%) absolute reduction in the acute cohort, and this reduction persisted. Starting a short-term, expensive medicine was also linked to 1.9% (95% CI, -3.3% to -0.6%) reduced odds of maintaining optimal adherence over the course of follow-up(26).

According to a study conducted at the Ramathibodi Hospital, Faculty of Medicine, Mahidol University, Bangkok, Thailand, patients who failed to adhere to their drug regimens well had longer illness and medication durations ($p = 0.005$). (22)

Gender

According to a study done in the US and Canada, women were significantly more likely than men to have higher taking adherence scores (OR, 3.03; 95% CI, 1.20–7.66) among participants aged 17 to 24, but gender did not appear to have an effect on taking adherence scores among participants aged 11 to 16(27).

INR result

Findings from the International Normalized Ratio Adherence and Genetics (IN-RANGE) Study conducted by the American Medical Association the participants' INR at each visit was the study's main finding. Underanticoagulation (INR below the lower limit of the INR range) and overanticoagulation (INR above the higher limit of the INR range) were

the two main ways to measure INR. In follow-up investigations, they looked at the relationship between adherence and more severe underanticoagulation results ($\text{INR} \leq 1.5$) as well as any out-of-range INR. Too few really high INRs ($n=24 >4.0$) existed to investigate this result. Under all categories where participants failed to open more than 20% of the pill bottles showed statistically significant relationships between underanticoagulation and underadherence. There was a 14% increase in the likelihood of underanticoagulation ($P < .001$) and a 10% increase in the odds of out-of-range INR ($P < .001$) for every 10% relative increase in missed pill bottle openings(10).

Socioeconomic status

In a cross-sectional study conducted in CHCs of Chatham County, Georgia regarding social and economic factors, a higher percentage of non-adherent participants reported difficulty affording medications (52.6% vs. 29.2%, $p < 0.01$) and difficulty with transportation to pick up medication at the pharmacy (57.7% vs. 36.1%, $p < 0.01$) when compared with 256 adherent participants.(28).

The results of the current investigation showed that patients with CVD who were using NOACs had high treatment adherence. In a study conducted in an inland city of the state of Sao Paulo, participants in a private cardiology clinic and public university hospital showed better adherence to new oral anticoagulants (NOACs) when they had follow-up at a public outpatient clinic, were female, had a higher family income, and were not employed. 13.3% of the subjects said they had stopped taking NOACs within the previous month. Of those who stopped therapy, more than half (62.5%) did so for reasons unrelated to the surgery or dental procedure, such as insufficient funds to purchase the medication; of those who stopped treatment, 60% went to the public clinic(29).

Parental marital status

An investigation carried out at Children's Hospital of the Mid-Atlantic There were no differences between the groups in terms of income, parent education, parent marital status, perceived level of care from primary or secondary caregivers, overprotection from the primary caregiver, and family functioning(30).

Taste of medication

Children's medications are available in a wide range of formulations, such as liquids, solids, powders, suspensions, and topicals. The adherence to these formulations is affected. A study conducted in pediatric ambulatory care clinics and waiting rooms for additional services by The Journal of Pediatric Pharmacology and Therapeutics This study involved 90 child-parent pairs, with a mean kid age of 6.7 ± 2.9 years and 58% female participants. There were no appreciable variations in the performance of the three scales ($p > 0.05$). Nonetheless, compared to children aged 5 and above ($r > 0.9$), the concordance between parental assignment and child ranks was much lower for 3- and 4-year-olds ($r < 0.4$ and $r < 0.6$)(31).

Parental education and distance from health care facility

Several other factors, such as young age, parental education level ($p=0.035$), combination of warfarin and aspirin, and missing anticoagulant dosages, also revealed a tendency for an association in a sub-Saharan African study on cardiovascular patients. There was a significant correlation ($p=0.003$) between less educational attainment, a greater distance from a medical facility, fewer follow-up appointments, and warfarin from public institutions and less-than-ideal INR control (32).

An estimated 5% of hospital admissions are attributed to noncompliance with drug therapy, resulting in a direct cost of approximately \$8 billion. Patients struggle mightily to adhere to their medication regimens, particularly those including warfarin, and this noncompliance significantly impairs anticoagulation control(10).

Awareness of children about their medical status

In a research done at Pusan National University Children's Hospital, the good adherence group had a significantly higher percentage of patients who knew the names of the medications they had previously taken and that of patients who were aware of the side effects of the medications ($P = 0.008$ and $P = 0.020$, respectively)(33).

In a study conducted at Mahidol University in Bangkok, Thailand, where patients with irregular medication use were interviewed, the researchers discovered that forgetfulness (63.46%) and ignorance of the significance of the medications (61.54%) were the two

leading causes of poor adherence. The fact that 34.61% of these patients' caregivers failed to give them their medication was another factor contributing to poor adherence, particularly in younger patients. Medication side effects accounted for 23.08 percent of the reasons people stopped taking the prescriptions(22).

According to a qualitative Oxford University study, communication between a child, their parents or other caregivers, and medical experts fosters confidence in the kid and is linked to increased adherence by raising awareness of the value of therapy and helping the child understand sickness. If caregivers were unable to explain the aim of the treatment, some children even reported resisting medication as a way to get more information.(34) The aim of this study is to know the magnitude and associated factors of anticoagulant non adherence so that we can establish a better anticoagulation control among pediatrics.

2.4 CONCEPTUAL FRAMEWORK

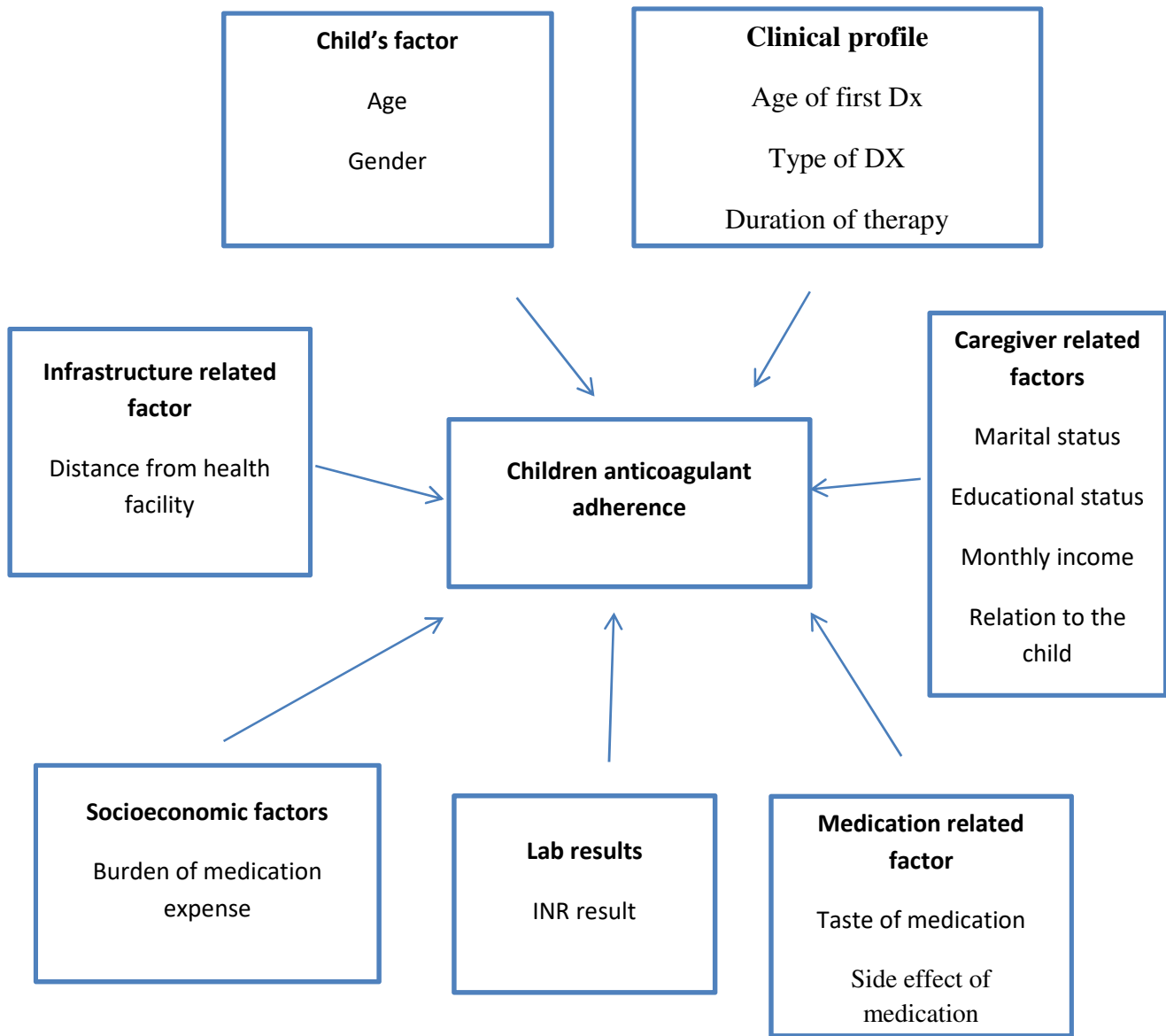


Figure 1 conceptual frame work

Conceptual framework shows relationship between the dependent and independent variables of anticoagulant adherence. It was adapted after reviewing different literatures (3) (10)(25)(31)(32)(21)(35)(36)(28)(29) (37)

CHAPTER THREE

3. OBJECTIVES

3.1 General objectives

- To assess the adherence of anticoagulant medication and its associated factors among children with cardiac problems attending cardiac OPD of selected public hospitals, Addis Ababa, Ethiopia, 2024

3.2 Specific objectives

- To determine the adherence of anticoagulant medications among children with cardiac problems attending cardiac OPD of selected public hospitals, Addis Ababa, Ethiopia, 2024
- To identify factors associated with children adherence to anticoagulant medications among children with cardiac problems attending cardiac OPD of selected public hospitals, Addis Ababa, Ethiopia, 2024

CHAPTER FOUR

4. METHODS AND MATERIALS

4.1 STUDY AREA

The study was conducted in selected hospitals Addis Ababa, Ethiopia. Addis Ababa is the Headquarter of the African Union, the third united nation population, and with representation from nearly every from embassy from around the world. The metro area population of Addis Ababa in 2022 was 5,228,000. It sitting at the foot of Mount Entoto at elevation of 2,355 meters. In Addis Ababa, there are around 12 public hospitals; from them by using a lottery method three Hospitals are selected. Such as: St. Paulo's Hospital Millennium medical college, St. Peter Hospital, and Cardiac Center Ethiopia.

Cardiac Center Ethiopia is located in Addis Ababa, Lideta Sub City, Woreda 09 Zambia Street. It was established in 2009 by Dr. Belay Abegaz. It is a charity organization, affiliated with public hospitals. Cardiac center is the first center in the country to activate cardiac surgery. The center has two pediatric OPD's an average of 50 patients seen in the outpatient department. There are 5 nurses and two physicians working there.

St. Paul's Hospital Millennium Medical College gained today name by a decree of council of minister in 2010. But the Hospital was established in 1968 by Emperor Haile-selassie and the medical school opened in 2007. The college has more than 2800 clinical, academic and administrative and support staffs that provide medical specialty services to patients who are referred from all over the country. It also one of largest referral hospital has more than 700 beds. The College sees an average of 1200 emergency and outpatient clients daily, an average of 104 children with cardiac problems are seen at OPD montly.

St. Peter Specialized Hospital established in June, 1961also largest referral hospital. It also provides varies Emergency, Inpatient, and outpatient service for different catchment area. Averagely 50 children with cardiac problems seen monthly in this hospital.

4.2 Study period

The study was conducted from May 1, 2024 – May 30, 2024 on children attending the facilities

4.2 Study design

An institutional based quantitative cross-sectional study design was used

4.3 source population

All children with cardiac problems attending selected public hospital OPD

4.4 Study population

The study population was all the children with cardiac problems who is on anticoagulant medications attending there follow up at CCE, SPSH and SPHMMC during the study period who fulfill the inclusion criteria

4.5 Study unit

Selected sample children who took anticoagulant medication

4.6 Inclusion and exclusion criteria

4.6.1 Inclusion criteria

- Children attending cardiac OPD during the time of data collection
- Children that are on anticoagulant medication
- Children under the age of 14

4.6.2 Exclusion criteria

- Children who are severally ill in data collection time

4.7 Sampling procedure

4.7.1 Sample size determination

All children who fulfill the inclusion criteria who were available during data collection time were taken for this study.

4.7.2 Sampling Technique

Study settings were selected using purposive sampling and survey method was applied all the children who are taking anticoagulant medication during the study period at the selected study areas were taken.

4.7.3 Sampling Frame

Purposive sampling was used in this investigation to choose the research areas. Considering that anticoagulants are typically administered following cardiac procedures and cardiac procedures were performed in these specific public institutions. Because of the potential for conflicting results from heterogeneous data, the private sector was not taken into account. All children available during data collection period at the data collection area were taken.

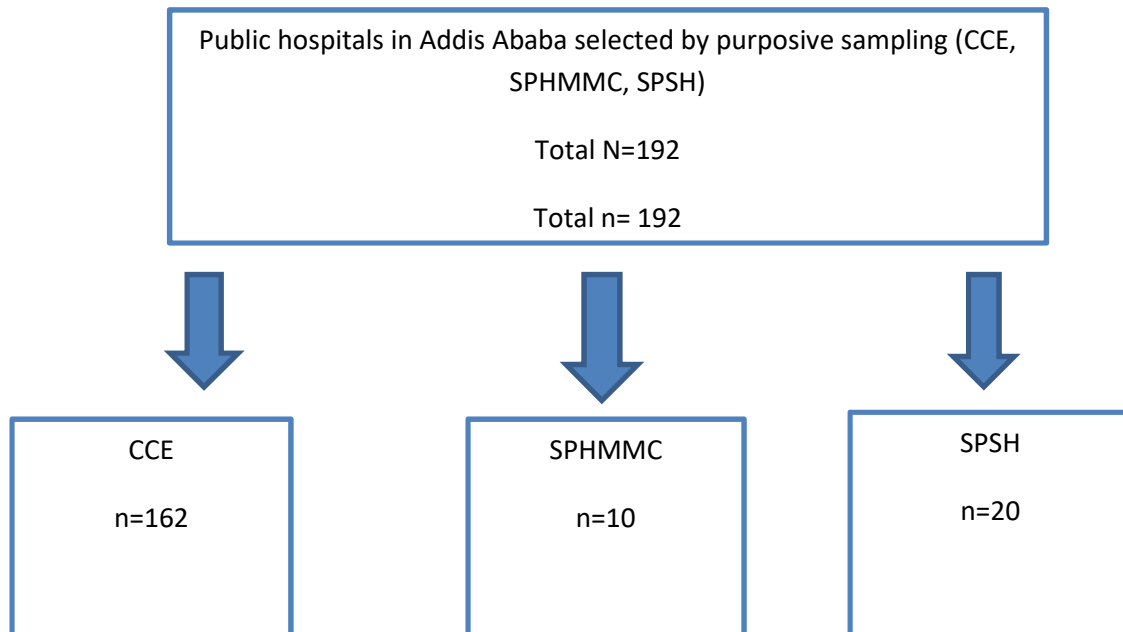


Figure 2: proportional allocation of sample

4.8 Variables of the study

4.8.1 Dependent variables

- Anticoagulant medication adherence

4.8.2 Independent variables

- Age
- Marital status of the parent
- Educational status of caregiver
- Monthly income of caregiver
- Distance of health care facility from home
- Gender
- INR result
- Age at first diagnosis
- Type of diagnosis
- Duration of therapy
- Relation with the child
- Burden of medication expense
- Taste of medication
- Side effect of medication

4.9 Operational Definition

- **Adherence:** the extent to which a person's behavior of taking medication corresponds with the recommendations from a health care provider.(38)
- **Good adherence of medication:** Adherence of medication measured as, caregivers self-report for anticoagulant medication who has been missed less than 3 doses in the past seven days and children with anticoagulant medications taken >95% of the prescribed doses categorized as Good adherence.(39)
- **Poor adherence:** adherence of medication measured as caregivers self-report for anticoagulant medication has been missed 3 doses and more than 3 doses in the past seven days and child with anticoagulant medication taken <95% of prescribed doses.(40)

- **Children:** child under the age of 14.(41)

4.10 Data collection method, tool, and procedures

A well-structured questionnaire that include the socio demographic parts of both the child and caregiver and adherence assessing questions that include the 7 day pill recall method adapted from other researches was used to interview the parents or caregivers of the children after obtaining oral consent. The questionnaire was pre-tested in children from Tazma Cardiac Center then the data was interred in SPSS for Cronbach's alpha reliability test with a cut of point of 70 and above which was 72 in this study. After pre-test data was collected by using primary data through interview. The questionnaire was prepared in English and translated in Amharic and the re-translated back to English to check its consistency. Data collectors from the facility collected the data. All caregivers who are present at the study areas at the study period were included.

4.11 Data quality control

Data collectors were assigned from cardiac OPD Bsc Nurses and one-day training was provided to achieve common understanding on the questionnaire and on the objective of the study. The questionnaire was pre-tested on 10% of the children attending the cardiac OPD of Tazma Cardiac center. Continuous supervision was made by the PI during data collection and the collected data was checked for completeness and accuracy during data collection period.

4.12 Data processing and analysis

The data was collected, coded cleaned and was entered using Epi-Info 3.1 then exported to SPSS version 25 software to be summarized, tabulated and analyzed. Frequencies, proportions, and dispersions were estimated to describe the variables.

Association between dependent and independent variables was assessed by using bivariate regression, the variables with P-value <0.2 were transported to multivariate analysis P-value < 0.05 were taken as statistically significant and to control confounders.

The assumption of logistic regression was checked on Hosmer-Lemeshow goodness of-fit-test which was 0.7. To exclude or control confounders' randomization of study factors were applied. Multicollinearity of independent variables was assessed by calculating

variance inflation factor (VIF) and Tolerance for each independent variable VIF being <10 and Tolerance >0.1. Adjusted odds ratio (AOR) was calculated to determine the association between the dependent and independent variables at 95% confidence interval (CI).

4.13 Ethical considerations

Ethical approval was obtained from St. Paul's Hospital Millennium Medical College and support letter from school of nursing department of Cardiovascular Nursing to Cardiac Center Ethiopia, SPHMMC and SPSH administrator office. All the participants were informed about the purpose of the study and verbal consent was secured from all participants prior to the starting of data collection. Privacy and confidentiality of information given by each respondent was maintained and names given were not recorded. Caregivers of the children had the right to reject or participate in the study.

4.14 Dissemination of results

The finding of this study will be compiled, summarized and disseminated to Cardiac Center Ethiopia and SPSH, SPHMMC department of adult health nursing and research publication offices and to those who will utilize the finding in one way or another as deemed necessary. Findings of non-adherence among the participants were reported to the clinical staff working in study area so that it can be resolved.

CHAPTER 5

5. RESULT

5.1 Socio Demographic Characteristics

In this study, 192 parents or other caregivers took part. Of this majority 112 (58.3%) were female. Three of them (1.6%) were older than 60, while the majority of them 99 (51.6%) were in the 20–39 age range. Of them, 89 (46.4%) were in the 40–59 age range. Ninety-six percent (174) of them were married. In terms of educational status, 42(21.9%) had no formal education, while 55(28.6%) had completed their tertiary education (diploma and above). 174 (90.6%) of their monthly income is less than 10,000 in Ethiopian currency.

Table 1: socio demographic characteristics of the children and parents at selected government hospitals Addis Ababa Ethiopia, June 2024

Variables		Frequency	Percentage
Age of children	2-3	4	2.1
	4-14	188	97.9
Gender of children	Female	107	55.7
	Male	85	44.3
Age of caregivers (parents)	<20	1	0.5
	20-39	99	51.6
	40-59	89	46.4
	>=60	3	1.6
Gender of caregivers (parents)	Female	112	58.3
	Male	80	41.7
Religion	Orthodox	89	46.4

	Muslim	53	27.6
	Protestant	41	21.4
	Catholic	9	4.7
Distance from health facility (hr)	<12hrs	161	83.9
	>=12hrs	31	16.1
Relation with the child	Mother	113	58.9
	Father	72	37.5
	Other	7	3.6
Marital status	Married	174	90.6
	Single	12	6.3
	Divorced	4	2.1
	Widowed	2	1.0
Parents educational status	No formal education	42	21.9
	Primary education(1-8 th grade)	53	27.6
	Secondary education (9-12 th grade)	42	21.9
	Tertiary education (diploma and above)	55	28.6
Monthly income	<10,000	174	90.6

>=10,000

18

9.4

5.2 Clinical Profiles of the Children

Hundred percent of the 192 children are taking Warfarin. About children's awareness of their medical conditions, 139 (72.4%) are aware of their conditions, whereas 53 (27.5%) are unaware of the diagnosis in reality. Regarding the duration of therapy, 56 (29.2%) have been on anticoagulant treatment for more than six months, while 136 (70.8%) have been on it for less than six months. Age of children when first diagnosed 126 (65.6%) were first diagnosed between the age of 4 and 14. The majority of the children 125 (65.1%) are diagnosed with Valvular heart disease.

Table 2: Clinical profiles of the children at selected government hospitals Addis Ababa, Ethiopia, 2024

Variables		Frequency	Percentage
Medical diagnosis	CHD	67	34.9
	VHD	125	65.1
Age of child when first diagnosed	<=1	34	17.7
	2-3	32	16.7
	4-14	126	65.6
Duration of anticoagulant therapy	<=6	136	70.8
	>6	56	29.2
INR result	1.4-1.9	97	50.5
	2.0-2.5	71	37.0
	2.6-3.0	22	11.5

	3.1-3.5	2	1.0
Awareness of the medical status	Yes	139	72.4
	No	53	27.6

5.3 Adherence Status of the Children

Out of all the participants in this study, 160 (83.3%) are taking anticoagulant therapy along with other medications. Of these, the majority—44 (22.9%)—are on Lasix, followed by 37 (19.3%) on B. penicillin, 36 (18.8%) on enalapril, 12 (6.3%) on ASA, and 31 (16.1%) on other medications. Only 32 individuals (16.7%) were using Warfarin only. If they do fail to give children their medication, the following are the main reasons: 132 (68.8%) miss due to simple forgetfulness; 20 (10.4%) due to caregiver absence; 16 (8.3%) due to travel; 15 (7.8%) due to a poor test; and 9 (4.7%) due to the child falling asleep to take their medication.

Table 3: Adherence status of the children in selected government hospitals Addis Ababa, Ethiopia, 2024

Variables		Frequency	Percentage
Medication return amount	<=5% of prescribed doses	164	85.4
	>5% of prescribed doses	28	14.6
Doses missed yesterday	None	177	92.2
	One	15	7.8
Doses missed before	None	177	92.2

yesterday	One	15	7.8
Doses missed 3 days ago	None	176	91.7
	One	16	8.3
Doses missed 4 days ago	None	177	92.2
	One	15	7.8
Doses missed 5 days ago	None	177	92.2
	One	15	7.8
Doses missed 6 days ago	None	180	93.8
	One	12	6.2
Doses missed 7 days ago	None	168	87.5
	One	24	12.5
Is there any side effects developed?	Yes	50	26.0
	No	142	74.0
Did the test of medication affect the child?	Yes	15	7.8
	No	177	92.2
Other medication the child is taking	Only warfarin	32	16.7
	Enalapril	36	18.8
	B.penicillin	37	19.3
	Lasix	44	22.9
	ASA	12	6.3

	Others	31	16.1
Reason for failing to give medication on time	Simple forgetfulness	132	68.8
	We travel	16	8.3
	Child was asleep	9	4.7
	Caregiver away	20	10.4
	Because of bad test	15	7.8

According to this study 85.4% of the total children with cardiac problems at selected government hospital have good adherence, the rest 14.6% have poor adherence.

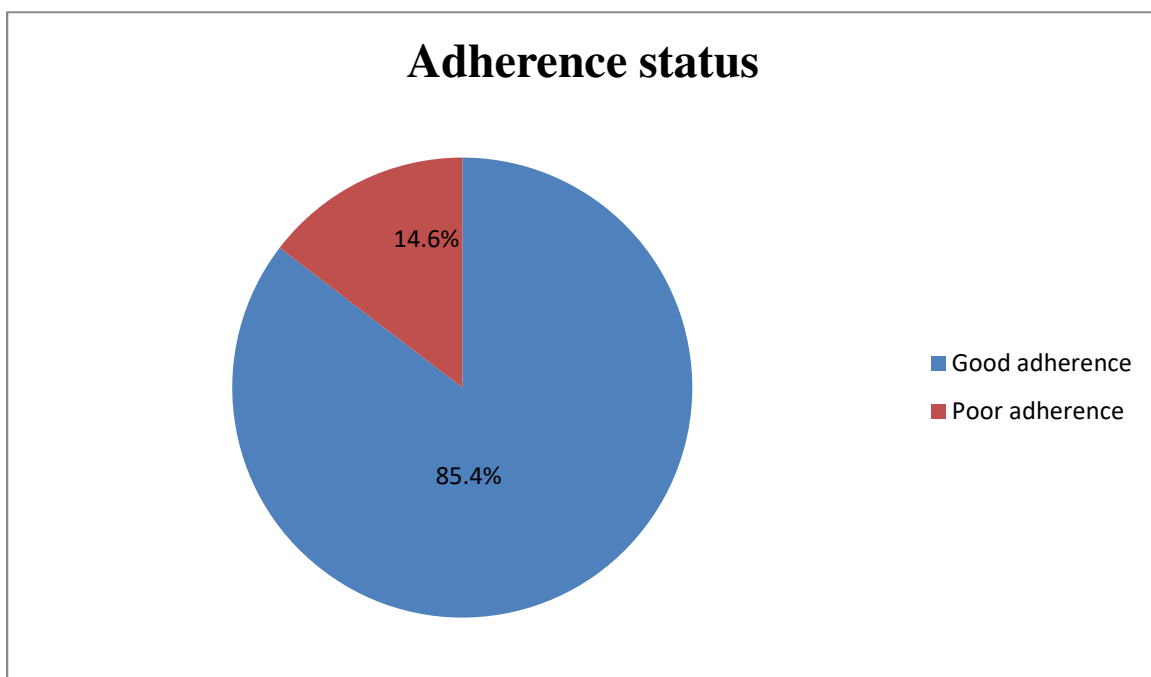


Figure 3: Pie chart shows adherence status of children with cardiac problems in selected government hospitals Addis Ababa, Ethiopia, 2024

5.4 Factors Associated with Poor Anticoagulant Adherence

The relationship between the dependent variable and the independent variables was examined using bivariate and multivariate analysis. The variables gender of the children, religion, relationship with the child, duration of therapy, awareness of their medical status, cause for missing a dose, and drug side effect pass the bivariate analysis with a cut point of P value <0.25. With a cut point P value <0.05, the variables awareness of their medical status and length of therapy have passed the multivariate analysis.

Compared to the adherence status of the children duration of therapy >6 months are (AOR: 0.118, 95% CI: 0.034-0.410) less likely to adhere to anticoagulant than those whose duration of therapy was ≤ 6months.

Children who are aware of their medical condition are (AOR: 0.043, 95% CI: 0.011-0.165) are more likely to adhere to anticoagulant therapy than those who are not aware of their medical condition.

Table 4: Multivariate Analysis of Adherence status with Socio demographic characteristics of children and caregivers

Variables	Category	Poor adherence		COR, 95%CI	P value	AOR, 95% CI	P value
		No	Yes				
Gender of children	Female	101(94.4%)	6(5.6%)	0.170(0.065-0.443)	0.000	0.347(0.101-1.194)	0.093
	Male	63(74.1%)	22(25.9%)	I	I	I	I
Religion	Orthodox	81(91.0%)	8(9.0%)	2.355(0.866-6.404)	0.093	0.90(0.006-1.339)	0.80

Relationship with the child	Muslim	43(81.1%)	10(18.9%)	2.848(1.010-8.029)	0.048	0.327(0.0025-4.255)	0.393
	Protestant	32(78.0%)	9(22.0%)	1.266(0.140-11.446)	0.834	0.598(0.043-8.274)	0.701
	Catholic	8(88.9%)	1(11.1%)	I	I	I	I
	Mother	101(89.4%)	12(10.6%)	2.215(0.970-5.057)	0.059	0.154(0.007-3.255)	0.30
	Father	57(79.2%)	15(20.8%)	1.403(0.155-12.660)	0.763	0.978(0.053-17.995)	0.230
	Other	6(85.7%)	1(14.3%)	I	I	I	0.701

Table 5: Multivariate analysis of adherence status with clinical profiles of the children

Variables	Category	Poor adherence		COR, 95% CI	P value	AOR, 95% CI	P value
		No	Yes				
Duration of therapy	<=6 months	124(91.2%)	12(8.8%)	0.242(0.106-0.554)	0.001	0.118(0.034-0.410)**	0.001
	>6 months	40(7.4%)	16(28.6%)	I	I	I	I
Awareness of their medical condition	Yes	133(95.7%)	6(4.3%)	0.064(0.024-0.170)	0.001	0.043(0.011-0.165)**	0.001
	No	31(58.5%)	22(41.5%)	I	I	I	I
Reason for missing a dose	Simple forgetfulness	119(90.2%)	13(9.8%)	2.112(0.532-8.395)	0.003	0.420(0.074-2.401)	0.330
	We travel	13(81.3%)	3(18.8%)	1.144(0.132-9.885)	0.201	0.957(0.094-9.724)	0.970
	Child was asleep	8(88.9%)	1(11.1%)	3.051(0.954-9.761)	0.158	0.192(0.92-3.139)	0.247
	Caregiver was away	15(75.0%)	5(25.0%)	6.103(1.873-19.881)	0.348	0.436(0.055-3.448)	0.431

	Because of bad test	9(60.0%)	6(40.0%)	I	I	I	I
Is there any side effect present	Yes	33(66.0%)	17(34.0%)	0.163(0.070-0.381)	0.000	2.449(0.796-7.538)	0.118
	No	131(92.3%)	11(7.7%)	I	I	I	I

**Significant in the multivariable binary logistic regression (p-value 0.05), AOR stands for adjusted odds ratio, COR for crude odds ratio, CI for confidence interval, I for reference.

CHAPTER 6

DISCUSSION

This study was conducted to assess the adherence of anticoagulant medication and its associated factors among children with cardiac problems attending cardiac OPD of Cardiac Center Ethiopia, St. Paul's Hospital Millennium Medical College and St. Peter's specialized Hospital, Addis Ababa, Ethiopia.

In this study when we see the overall adherence of the children (n=192) 85.4% were adherent to anticoagulant treatment. In a Cincinnati, Ohio study on pediatric medication adherence obstacles (n=161), Patients and caregivers stated that they or their kid took 96% of the prescribed dosages.(23) This could be due to the difference in the population of the study. A study at the Faculty of Medicine, Ramathibodi Hospital, Mahidol University, Bangkok, Thailand, found that, according to the pill count technique, 158 patients (75.24%) had good adherence to medical therapy.(22) This could be because the study stated above was conducted in overall medication adherence among children with a cardiac problem.

According to this study, children's not aware of their medical condition were 0.043 (95%) times less likely to adhere anticoagulant medication compared to children's who have awareness of their medical condition. The result found agrees with some of the result found in England, a qualitative study conducted at Oxford University, children who understood the nature of illness and the significance of treatment improved their adherence (34). This result is also supported by a research done at Pusan National University Children's Hospital, the good adherence group had a significantly higher percentage of patients who knew the names of the medications they had previously taken and that of patients who were aware of the side effects of the medications(33). Therefore, healthcare providers should prioritize patient education and counseling as a key strategy to improve adherence rates, potentially reducing the risk of complications associated with non-adherence, such as thromboembolism and its long-term consequences.

This study indicates that those participants whose duration of therapy >6 months were 0.118 (88.2%) times less likely to adhere anticoagulant medication compared to anticoagulant medication adherence ≤ 6 month. This is consistent with other finding like, a study conducted in US, children starting a high-cost long-term medication were related with a 1.9% fall in adherence and maintained absolute reduction in adherence when compared to adherence among children began at low-cost long-term medication, according to a study done by a national US health insurer.(26)

Whereas according to a study conducted at the Ramathibodi Hospital, Faculty of Medicine, Mahidol University, Bangkok, Thailand, patients who failed to adhere to their drug regimens well had longer illness and medication durations.(22) Developing strategies to support children and their families throughout prolonged treatment periods, possibly incorporating regular follow-ups, counseling, and adherence reminders to sustain engagement over time. By addressing this factor, healthcare systems can improve anticoagulant adherence rates, ultimately leading to better health outcomes for children undergoing anticoagulant therapy.

CHAPTER 7

7.1 CONCLUSION

Among the children with cardiac problems on follow up at cardiac OPD of selected public hospitals in Addis Ababa 14.6% were not adherent to the anticoagulant medication they were taking. Furthermore duration of therapy and awareness of the children about their medical condition significantly increased the likelihood of non-adherence in children with cardiac problems.

Non-adherence to anticoagulant medications can have serious consequences, given the critical role these drugs play in preventing thromboembolic events such as strokes, deep vein thrombosis (DVT), and pulmonary embolism (PE). Non-adherence to anticoagulants medications can increase hospitalization, mortality and complications in children.

Managing anticoagulant treatment adherence can improve the quality of life of children with cardiac disease; it can prevent complications and manage medical condition effectively. It can also reduce cost of medical service and reduce anxiety and stress in children and parents.

7.2 Limitation

Limitation

- As a cross-sectional study, it captures adherence behavior and associated factors at a single point in time, limiting the ability to infer causality or track changes over time.

7.3 RECOMMENDATION

For Healthcare Providers:

- **Counseling**
 - Provide clear and age-appropriate counseling to both children (when appropriate) and their caregivers about the importance of anticoagulant therapy, potential side effects, and the risks of non-adherence.
- **Regular Monitoring and Follow-Up**
 - Schedule frequent follow-up appointments to monitor adherence and any side effects.
- **Psychosocial Support**
 - Provide psychological support to children and their families to address any anxiety, stress, or depression related to the medical condition and its management.
- **Individualized Care Plans**
 - Develop personalized care plans that consider the child's specific medical condition, family dynamics, and socioeconomic factors.

For Caregivers and Families:

- **Create a Supportive Environment**
 - Establish a routine for medication administration, integrating it into daily activities to make it a consistent habit.
 - Use medication reminders such as alarms, calendars, or mobile apps to ensure doses are not missed.
- **Involve the Child**
 - Educate the child about their condition and treatment in an age-appropriate manner to foster a sense of responsibility and understanding.
 - Encourage older children and adolescents to take an active role in managing their medication.
- **Collaboration with Schools**
 - Communicate with school staff to ensure they are aware of the child's medication needs and can provide support during school hours.
 - Provide the school with necessary information and medications in case doses need to be administered during the day.

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41. Ethiopia Age structure - Demographics.

ANNEX I- Consent Form

St. Paul's Hospital Millennium Medical College Adult Health Nursing Department

Information Sheet and Consent form for study participants to assess, adherence to anticoagulant medication and its association factors among children attending cardiac OPD at selected public hospitals, Addis Ababa, Ethiopia

Name of Principal investigator- Gelila Kassahun

Introduction

This information sheet and consent form is prepared by the principal investigator to clarify the study that you are asked to take part. If there is anything not clear before you decide to participate you are welcome.

Purpose

The main purpose of this research is to assess the adherence of anticoagulant medications and its associated factor among children. This finding will help me to identify the magnitude of the problem and help me to take corrective actions.

Procedure

If you are willing to participate in this project, you will be interviewed by the data collector.

Confidentiality

The information that we will gather from this research will be kept confidential, and used only for research purpose. Your participation in this research is fully based on your willingness. Please take a few minutes to complete this questioner your name will not be written on this form, and will never be used in connection with any of the information you deliver. Your honest answers to these questions will help me to better understand the magnitude of non-adherence and adherence and associated factors among children taking anticoagulant medications. I would greatly appreciate your help in responding to this questioner. The questioner will take about 10 minutes to answer the questions.

Risks

There is no possible risk associated with participating in this study except the time spent for completing the questionnaire.

For any questions needed to ask you can use

Gelila Kassahun

Email: gelilakassahun95@gmail.com

Cell phone: 0920969889

ANNEX II- English Questionnaire

Prepared questionnaire for research (English version)

St. Paul's Hospital Millennium Medical College department of Adult Health Nursing
Questionnaire for the study at Cardiac Center Ethiopia, SPSH and SPHMMC cardiac
OPD.

Good morning/ Afternoon?

I am the student of SPHMMC and currently I am MSC graduating student. I am conducting a research on adherence of anticoagulant medication and its associated factor among children at Cardiac Center Ethiopia, SPSH, and SPHMMC cardiac OPD.

This finding will help me to identify the Impact and taking corrective actions during children follow-up. To attain this purpose your honest and genuine participation is very important and highly appreciable as possible. Please be assured that all the information gathered will be kept strictly confidential. Only the researcher has the access of the information and used it for the study purpose only. You have a full right and decision to not respond all the questions or partly. Are you willing to participate?

Yes

No

Data Collector Name _____ Signature _____ Date _____

Supervisor Name _____ Signature _____ Date _____

PART ONE

Socio demographic data of the children

No.		
1.	Age	
2.	Gender	A .male B. Female
3.	INR result	
4.	1. Distance of health facility from home(hrs)	

Socio demographic data of the caregivers/ informants

No.		
1.	Age.....	
2.	Gender	A. Male B. Female
3.	Educational status	A. No formal education B. Primary education (1-8 th)

		grade) C. Secondary education (9-12 th grade) D. Tertiary education (Diploma and above)
4.	Religion	A. Orthodox B. Muslim C. Protestant D. Catholic E. Others
5.	Marital status	A. Married B. Single C. Divorced D. Widowed E. Other
6.	Medical diagnosis	
7.	Age of diagnosis	
8.	For how long was the child on anticoagulant therapy	
9.	Which medication is the child on	A. Heparin B. Warfarin C. Other.....
10.	Does the child know his/her medical condition	A. Yes B. No
11.	What is your monthly income in	A. <10,000 B. 10,000 – 42,866

	Ethiopian Birr	C. > 42,866
12.	Burden of medication expenses	A. None B. Rarely C. Sometimes D. Often E. High
13.	Relation with the child	A. Mother B. Father C. Non biological parents

PART TWO

Assessment of adherence and non- adherence

No.		
1.	Do you have medication with you? May I see them? Medication return amount	A. $\leq 5\%$ of prescribed dose B. $> 5\%$ of prescribed dose C. The one day dose
2.	Can you tell me when you give the child medication	A. Morning B. Afternoon C. Evening D. Morning and evening E. Other.....
3.	How many doses did the child miss taking yesterday	A. None B. One C. Two

4.	How many doses did the child miss taking day before yesterday	A. None B. One C. Two
5.	How many doses did the child miss taking 3 days ago	A. None B. One C. Two
6.	How many doses did the child miss taking 4 days ago	A. None B. One C. Two
7.	How many doses did the child miss taking 5 days ago	A. None B. One C. Two
8.	How many doses did the child miss taking 6 days ago	A. None B. One C. Two
9.	How many doses did the child miss taking 7 days ago?	A. None B. One C. Two
10.	Are there other medications the child is taking currently?	A. Yes B. No
11.	If yes for the above question what are the medications?	
12.	If you sometimes miss a dose, could you tell me the cause	A. Simple forgetfulness B. We travel C. Child was asleep D. Caregiver away E. Because of bad test

		F. Medication is too expensive
13.	How often the drug is ordered to be taken by the doctor?	A. Daily B. As needed C. Don't know
14.	Is there any drug side effects	A. Yes B. No
15.	Does the taste of the medication affect the child?	A. Yes B. No

Declaration

I declare that this Research proposal entitled “Adherence to Anticoagulant Medication and its Associated Factors Among Children with Cardiac Problems attending Cardiac OPD at Selected Public hospitals, Addis Ababa, Ethiopia” is my own work that have not been addressed in the study area as far as my knowledge touched and all the sources I used has been indicated and acknowledged as complete reference.

Name of investigator

Signature

Date

Gelila Kassahun

Name of adviser/s

1. _____

2. _____

Name of invigilators

1. _____

2. _____

