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ASSESSMENTS OF COAGULATION PROFILE AMOUNG ADULT CARDIAC OUTPATIENT DEPARTMENT OF TIKUR ANBESSA HOSPITAL, ADDIS ABABA, ETHIOPIA

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ACRONYMS

AAU	Addis Ababa university
AF	Atrial Fibrillation
APTT	Activated partial thromboplastin time
BT	Bleeding time
BSC	Bachelor of Science
CHF	Congestive heart failure
CPB	Cardio pulmonary bypass
DGC	Departments graduate committee
DIC	Disseminated intravascular coagulation
DR	Doctor
DVT	Deep vein thrombosis
ED	Emergency department
FDA	Federal drug administration
FDPs	Fibrinogen degradation products
GC	Gregorian calendar
IHD	Ischemic heart disease
INR	International normalizedratio
MD	Medical doctor
MOH	Ministry of health

NGO	Nongovernmental organization
OAC	Oral anticoagulant
PE	pulmonary embolism
POC	Point of care
PT	Prothrombin time
RHD	Rheumatoid heart disease
SIRS	Systemic inflammatory response syndromes
SE	Systemic embolism
TT	Thrombin time
UK	united Kingdom
USA	united state of America
VTE	venous thromboembolism

TABLES OF CONTENTS

Contents

LIST OF TABLES AND FIGURES

ABSTRACT

Background; the coagulation process is initiated by platelets forming a plug at the location of the injury within few seconds of a breach in the vascular integrity. This constitutes the primary haemostatic mechanism. Secondary homeostasis is a multifaceted interaction between plasma coagulation factors, which results in the creation of fibrin strands strengthening the platelet plug. A hospital based cross sectional (retrospective chart review) study design was employed and simple random sampling techniques was used. Sample size is calculated by taking assumptions of 95% confidence level, there is no other study conducted related with this title to being use as a reference proportion so I took 50% (P=0.5) as a reference proportion. And adding 10 % non-respondents rate. The total population under study, which means total patient number who attend cardiac clinic in last month, was 1000 so by using correction formula the sample size becomes 306.

In this study we found that the mean INR value of a patient under study was 3.037 (SD: ±1.43) and the median was 2.9.While the quarantines was 2.0 – 3.65. According to our study, the data confirmed that the mean platelet count of the study unit was 282248(SD: ±89589). However, the mean PTT value of patients was 41.7 seconds (SD: ±11seconds). While the minimum PTT was 22 seconds and the maximum was 77 seconds. as this study is hospital based with limited representativeness population based studies are recommended.

Keyword: coagulation profile, platelets, hemostasis

1. INTRODUCTION

1.1. BACKGROUND INFORMATION

As we know from our clinical practice or experience the coagulation process is the most important part of our normal physiology which initiated by platelets forming a plug at the location of the injury within few seconds of a breach in the vascular integrity. This constitutes the primary haemostatic mechanism.[1] Secondary haemostasis is a multifaceted interaction between plasma coagulation factors, which results in the creation of fibrin strands strengthening the platelet plug.[1] under normal physiology, there is a compensation between different factors involved in haemostasis, and mild impairment of one component can be compensated by other factors.[2] Individuals with mild coagulation impairment may never present with significant bleeding unless exposed to trauma or major surgery.[2]Detailed family history might expose a significant bleeding disorder.

Haemostasis is a combination of a number of events that occur in a sequence following the breach of vascular integrity. They include vasoconstriction, platelet aggregation, thrombus formation, recanalization and healing. Conventionally, secondary haemostasis was described as intrinsic and extrinsic pathways merging at a final common pathway. [1]

This *in vitro* model ignores the link between primary and secondary haemostasis and is not applicable *in vivo*. The currently employed cell based model of coagulation reflects the *in vivo* process and it differs from the previous model in two key ways.

First, the complex formed by the tissue factor and factor VII contributes in the activation of factor IX, demonstrating that the intrinsic and extrinsic coagulation pathways are interconnected almost from the beginning of the process. Second, the complete process requires three consecutive phases: An initial phase, an amplification phase, and the propagation phase. Platelets and thrombin are actively involved in the last two phases.

A plethora of coagulation tests is available in the peri‐operative period to assist the clinician in identifying coagulation abnormalities. In recent years, incorporation of various forms of coagulation monitoring has provided valuable information in the management of peri‐operative coagulopathies.

From our day to day activity it is easy to understand perioperative coagulation management is a complex task that has a significant impact on the perioperative journey of patients. Anesthesia providers and perfusionists play a critical role in the decision-making on transfusion and/or haemostatic therapy in the surgical setting. Various tests are available in identifying coagulation abnormalities in the perioperative period. While the rapidly available bedside hemoglobin measurements can guide the transfusion of red bloodcells, blood product administration is guided by many *in vivo* and *in vitro* tests.

As we observed recently the introduction of newer anticoagulant medications and the implementation of the modified *in vivo* coagulation Cascades have given a new dimension to the field of perioperative transfusion medicine. A proper understanding of the application and interpretation of the coagulation tests is vital for a goodperioperative outcome. [03]

Oral anticoagulants (OACs) are indicated for the treatment of thrombosis and in the prevention of thromboembolism. This includes the treatment of deep venous thrombosis (DVT) and pulmonary embolism (PE), prevention of thrombosis in medically ill and postsurgical patients, and the prevention of thromboembolic stroke in atrial fibrillation.

Patients using OACs are likely to be seen in the emergency department (ED) for the same reasons as other individuals of similar age and health, but also because all anticoagulant therapies carry a riskof treatment-related bleeding that, if it occurs, mayrequire emergent evaluation and treatment. [4-7]

Clinical implications of clotting screens

Differentprotocols and guidelines which suggested that the importance of screening patients clotting conditions prior to surgery andClotting screens are often requested in hospitals for a wide variety of reasons. These include

(i) screening for investigation of a bleeding disorder,

(ii) prior to surgeries or procedures to determine an individual's bleeding risk,

(iii) patients with active bleeding to identify an abnormality in the coagulation system and guide replacement with fresh frozen plasma and

(iv) As a routine blood test. [8]

1.2 STATEMENT OF THE PROBLEM

It is clear to understand as a one parts of cardiac team patients undergoing cardiac surgery with cardiopulmonary bypass (CPB) are at increased risk for excessive perioperative blood loss requiring transfusion of blood products. Strategies to optimize administration of heparin and protamine and the assessment of their effects on coagulation are evolving in cardiac surgical patients.

Two recent evaluations have focused on the use of multiple point-of-care (POC) coagulation assays for patient- specific adjustment of heparin and protamine dosage. These studies indicate that blood loss and transfusion requirements in cardiac surgical patients may be reduced with more accurate control of heparin anticoagulation and its reversal. Blood component administration in patients with excessive post-CPB bleeding is generally empiric in part, related to turnaround times of laboratory-based tests. Methods are now available for rapid, POC assessment of coagulation to allow appropriate, targeted therapy for acquired hemostatic abnormalities.

Recent studies indicate that a rapid evaluation of thrombocytopenia and coagulation factor deficiencies with POC tests can facilitate the optimal administration of pharmacologic and transfusion-based therapy in patients who exhibit excessive bleeding after CPB. POC tests that assess platelet function have been developed, and their use may facilitate identification of which Patients at risk for excessive blood loss may respond to pharmacologic interventions such as desmopressin acetate or ant fibrinolytic agents. [9]

Why assessing coagulation Activity?

1. The patient has unintentionally or intentionally overdosed on the OAC, but there are no related symptoms, for example, in the case of warfarin, the patient's routine monitoring could have given an overly elevated INR value, which might be owing to an overdose or a pharmacological interaction.

2. The patient is experiencing a spontaneous episode of external or internal bleeding, or the latter may be suspected.

3. The patient has suffered an injury causing external or internal bleeding.

4. An urgent surgical or other invasive procedure is deemed necessary because of trauma or acute illness, and it is essential for the surgical team to know the level of anticoagulation. (3)

1.3 SIGNIFICANCE OF THE STUDY

Preoperative screening tests of hemostasis and coagulation is still considered by many as a standard practice before surgical procedures and cardiac intervention in an attempt to assess a patient's bleeding risk. In our setup current evidence does not support this routine practice of coagulation testing, which has a significant impact on the perioperative outcome. (9)
It may delay surgery, and patients may be subjected to unwarranted negative complications and preventable adverse events.

As bleeding be a most common surgical concern, yet is among the least studied while the most neglected among researchers and clinicians. In Ethiopia, only few studies in some parts have tried to examine things which relay on assessing coagulation profiles of patients.

Above all there are no other studies that have examined coagulation profiles of patients in any teaching hospitals of Ethiopia. Therefore, this study was intended to fill this information gap by assessing coagulation profiles of amongadult cardiac outpatient department in TikurAnbessa hospital, which can hopefully represent other hospitals in this country, and update the previous knowledge on the same problems.

2 LITERATURE REVIEW

Themechanism of blood coagulation is a complex and dynamicinteraction of platelets, plasma, and blood vessel endothelium.Blood coagulation is an important part of hemostasis process.

It is usually initiated through damage to the vessel wall andsubsequent activation of protease enzymes and ends with thetransformation of soluble fibrinogen into insoluble fibrin. [10]

A common model used to describe the mechanism of coagulation is the cascade system, which is separated into 3 areas. The intrinsic system commonly measured by the activated partialthromboplastin time (APTT) is activated by surface contact.

The extrinsic system, commonly measured by the prothrombintime (PT) test, is activated by vascular injury. The intrinsic and/or extrinsic pathway activates the common pathway leading to clot formation. The coagulation screening test such as PT, APTT, thrombin time (TT), and fibrinogen are important for the basic assessment of hemostasis.

The study conducted in India on January 2019 for 600 male volunteers, the mean of PT, APTT, TT, and fibrinogen in the blood samples of volunteers in plains were 13 s, 34 s, 17.3 s, and298 mg/dl (19 s), respectively. And Ninety-seven percent of PT, 95.2% APTT, 93.3% of TT, and 97.5% fibrinogen lie within range. [11]

Preoperative screening tests of haemostasis and coagulation is still considered by many as a standard practice before surgical procedures in an attempt to assess a patient's bleeding risk. Current evidence does not support this routine unselected coagulation testing, which has limited impact on the perioperative outcome.

It may delay surgery, and patients may be subjected to unwarranted tests. [12] Some of the early literature supported the application of the prothrombin time (PT) and the activated partial thromboplastin time (aPTT) in the preoperative assessment of coagulation.[13,14] If the clinical history and physical examination do not predict an increased risk of bleeding, abnormal operative hemorrhage is highly unlikely and hence, no further coagulation testing would be required. [15]

A systematic review on the guidelines assessing preoperative bleeding risks has recommended against the use of indiscriminate coagulation screening prior to procedures in an attempt to determine the bleeding risk.[16] This review further emphasizes that a bleeding history, which includes family history of coagulation disorders, abnormal bleeding with previous procedures, and concomitant use antiplatelet and antithrombotic medications should be obtained in every

patient before invasive procedures. Therefore, screening tests of coagulation such as PT, aPTT, platelet count and additional tests should be ordered only if the history and examination suggests an increased bleeding risk. This principle emulates the position of the American Society of Anesthesiologists. [17]

As we know patients, who are on the anticoagulant medication is more vulnerable to bleeding crisis than people who are not used or took any anticoagulation medication. In a prospective observational study in the UK, warfarin was implicated in 10.5% of adult hospital admissions for adverse drug reactions over a 6-month period ending in April 2002. [18]

Following a survey (2004–2005) of nationally representative public health surveillance data in the USA, which disclosed that warfarin, was implicated in 17.3% of ED visits for adverse drug events in older adults, Budnitz et al. [19]

Additionally one study conducted in USA shows that More than 90% of warfarin-related emergency hospitalizations in older patients are attributed to unintentional overdose. [19]

The study conducted in America, Colorado on twelve-month Outcomes and Predictors of Very Stable INR Control in Prevalent Warfarin Users showed that Bleeding and thromboembolic complications were significantly lower in stable vs. comparator patients (2.1% vs. 4.1% and 0.2% vs. 1.3%, respectively; $p < 0.05$). [24] so this paper showed that the necessity of knowing patient coagulation status prior to any procedure will prevent post op bleeding complication especially for the patient who had took any anticoagulants and those who will gone through open heart surgery via CPB machine.

Others special considerations of coagulation issues

Liver disease

Liver disease is a serious confounding issue in interpreting coagulation tests. Not only is the liver the principal source of most coagulation factors, but the reticuloendothelial system clears the products of anticoagulation and fibrin degradation. [20]

Sepsis and the systemic inflammatory response

SIRS results in a hypercoagulable state. In the critically ill patient, alterations in the coagulation cascade should be understood within this context. Thus, DIC is not generally an isolated derangement of coagulation, but frequently a measure of a profound inflammatory response. Its treatment should involve not only judicious replacement of consumed coagulation factors but a search for and treatment of an underlying inflammatory focus. [21, 22]

Massive transfusions and hypothermia

Massive transfusions may lead to a dilutional thrombocytopenia, provide an excess of citrate anticoagulant, and lead to lowered body temperature. Blood will tend not to clot in the hypothermic patient: body temperature is a crucial concern in the bleeding critically ill patient, particularly in those undergoing massive fluid replacement.

Medications and illnesses which depress platelet function

Many medications can depress platelet function, particularly the nonsteroidal anti-inflammatory agents, but also beta-lactam antibiotics (penicillins, cephalosporins), calcium channel blockers, and nitrates. Equally, renal failure and uremia can disturb platelet function. [22]

Cardiopulmonary bypass

CPB hasa significant impact on a patient coagulation process so special note should be made of patients who have undergone cardiopulmonary bypass. During bypass, there is activation of coagulation, conventionally by contact (intrinsic) pathway activation but also via extrinsic pathway induction of tissue factor on circulating monocytes. PT and PTT values should be monitored post operatively, and do appear to discriminate “bleeders” from “non-bleeders”. [22] As a rule such activation is transient, and PT and PTT values return to normal by 12 hours post operatively. [22]

2.1. CONCEPTUAL FRAME WORK

The conceptual frame work of this study illustrates coagulation profile .Coagulation profile is dependent variable and socio-demography, uses of Anticoagulant, recent history of transfusion and liver disease, cardiac disease are independent variables.

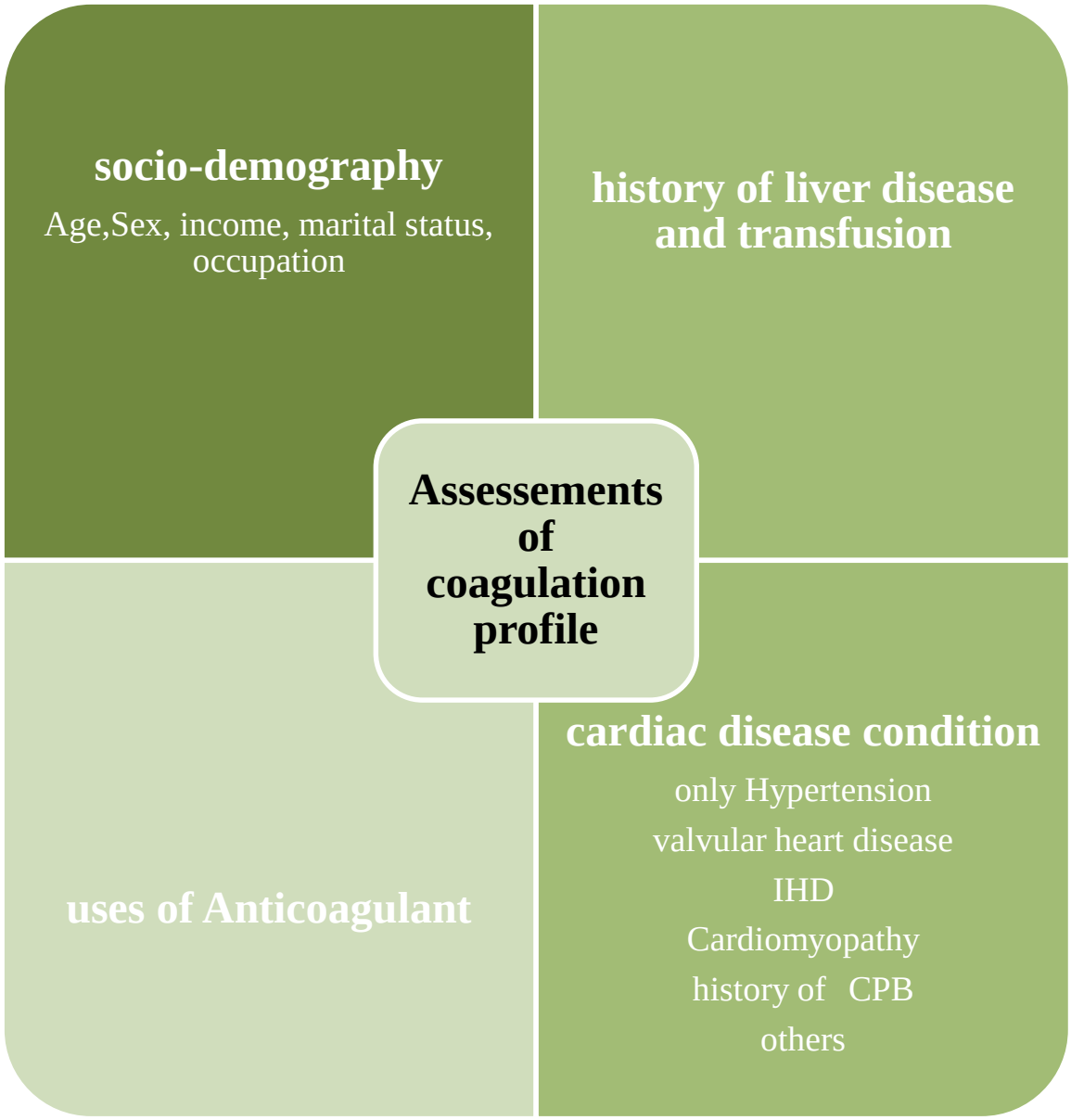

Figure.2.1. a conceptual model illustrating assessments of coagulation profile developed after reviewing literatures.

3. OBJECTIVES

3.1 GENERAL OBJECTIVES

To assess coagulation profiles among adult cardiac outpatient department of Tikur Anbessa hospital, Addis Ababa, Ethiopia, November 2020 G.C.

3.2 SPECIFIC OBJECTIVES

To determine mean coagulation profiles among adult cardiac outpatient department of Tikur Anbessa hospital, Addis Ababa, Ethiopia, November 2020 G.C.

3.3 OPERATIONAL DEFINITIONS

Coagulation profileis screening test or clotting measurements to identify the presence or absence of abnormal blood clotting. It includes INR, PTT and Platelets count.

Cardiac patient is a person with a class of diseases that involve the heart and blood vessels. It includes hypertensive heart disease, RHD, IHD, arrhythmia, CHF, congenital heart diseases and others.

4. METHODOLOGY

4.1 DESCRIPTION OF STUDY AREA

The study was conducted in Tikur Anbessa hospital which is located on capital city of Ethiopia, Addis Ababa and which is one of the colleges of Addis Ababa University under colleges of health science and it has four departments and sub divided into different sub units with its specialty. Addis Ababa is the largest city in Ethiopia, with a population of 3,475,952 according to the 2007 population census. Addis Ababa has 41 hospitals (13 public and 28 NGO and private), 29 health centers 122 health stations, 37 health posts and 382 modern private clinics. (23)

4.2 STUDY DESIGN

A hospital based cross sectional (retrospective chart review) study design was employed.

4.3 SOURCE POPULATION

The source population was all charts of adult outpatient departments who attended cardiac clinic from November 1 up to 30, 2020atTikurAnbessa hospital, Addis Ababa, Ethiopia.

4.4 STUDY POPULATION

The study populations were all the selected charts of adult outpatient departments who attended cardiac clinic from November 1 - 30, 2020 and have coagulation profile test, in Tikur Anbessa hospitals, Addis Ababa, Ethiopia.

4.5 SELECTION CRITERIA

4.5.1Inclusion Criteria

Selection of the sample

- Thedata collectors reviewed patient register book and identify MRN of charts of patients who attended cardiac clinic in the study period and they numbered them.
- The study units were selected from counted chart frame using simple random sampling
- Following the selection of MRN of charts, data collectors were got charts of patients and reviewed the history, laboratory results, decision notes, progress notes and operation notes.

- The selected charts were given study identification number to be used on the questionnaire for anonymity.
- The selected charts were had a complete history sheet and recent coagulation test to be included in the study.

4.5.2. Exclusion Criteria

- Charts, which lack complete information.
- Lost cards or folders from the card room or the systems.

4.6. SAMPLE SIZE DETERMINATION

Sample size is calculated taking assumptions of 95% confidence level, there is no other study conducted related with this title to being use as a reference proportion so I took 50% (P=0.5) as a reference proportion. And adding 10 % non-respondents rate. The total population under study, which means total patient number who attend cardiac clinic in last month, was 1000 so by using correction formula the sample size becomes 306.

4.7. SAMPLING TECHNIQUES

Simple randomsampling techniques used to select study charts. Additionally chart numbers of the patient from monthly report of cardiac OPD registration bookused to select the study unit (charts). Sothe formula used to select the sample from the sampling frame is K= N/n = 1000/306 = 3.26 and every 3 rd charts interval study sample was selected from the total monthly report of cardiac OPD registration book.

4.8. STUDY VARIABLES

4.8.1. Dependent variable

Coagulation profile

4.8.2. Independent variables

Socio-demography

Age, Sex, income, marital status, occupation

History of liver disease and transfusion

Cardiac disease condition

Only Hypertension, valvular heart disease, IHD, Cardiomyopathy, history of CPB

4.9 DATA COLLECTION TOOLS

Structured questionnaire and checklist which is developed by reviewing literature andused to collect data on assessments of coagulation profile in TikurAnbessa hospital. It was developed in English language.

4.10 DATA COLLECTION PROCESS

Two individuals who have completed their BSc in nursing education from a recognized University were recruited and the hospital's chief executive officer and head of the outpatient department were met and asked for permission. The data collection was held for a total of 15 days.

4.11 DATA QUALITY CONTROL AND ASSURANCE MANAGEMENTS

The data collectors were trained for two days on techniques of sampling, data collection and important points. The researcher was visiting the data collectors once a day to check if they collect the data appropriately. The researcher was evaluating the data during the data analysis stage to verify the completeness of the collected data. Pretest was carried out on 10% of the sample one month before the actual data collection in Tikur Anbessa hospital and the questions were revised based on the response obtained.

4.12 DATA ANALYSIS PROCEDURE

The data was first recorded and cleaned then analyzed using SPSS version 23 software statistical packages. Frequency used to describe the study population in relation to relevant variables. Results presented using tables, figures and texts.

4.13 EXPECTED OUTCOME

The Ethiopian government in general (MOH) and other concerned body especially in particular need to have scientific bases on the assessments of coagulation profile for which this study will supply valuable information. The result will also be used as baseline information for policy makers and further large-scale studies on the same problem.

4.14 DISSEMINATION PLAN

The result of the study will be presented to the public defense and following which the final revision will be disseminated to Addis Ababa University, School of Medicine,Department of Surgery, Cardiothoracic unit through hard copies. Dissemination of the result will also made to through hard copies or soft copies to those governmental and nongovernmental organizations that potentially will benefit from the study result.

5. ETHICAL CONSIDERATIONS

Ethical clearance secured and official letter of permissions was obtained from Department of graduate committee (DGC) of Addis Ababa University, College of health science, School of medicine. Similarly, Permission letter was obtained from TikurAnbessa, Hospital administrators and submitted to departments to whom study was conducted. Information was collected anonymously and confidentiality assured throughout the study per

6. RESULTS

6.1. SOCIO-DEMOGRAPHIC DATA

A total of 306 participants were included in the study. The mean age of the study subjects was 42 years old (SD ± 17years old) and 188(61.4%) were females. The majority of study participants were nongovernmental workers by their occupation 153 (50%) living in Addis Ababa region 139(45.4%) and 93(30.4%) of study subjects had <1000 ETB monthly income.

Table 6.1: Demographic composition of patients under study

Age description				
	N	Range	Mean	Standard deviation
Ages of patients	306	88-15=73 years	41.95	17.42
Sex distribution of study subjects				
Sex	Frequency	Percent		
Male	118	38.6		
Female	188	61.4		
Total	306	100		

Marital status		
Status	Frequency	Percent
Single	95	31
Married	188	61.4
Divorced	3	1
Widowed	20	6.5
Total	306	100
Income status		
Status	Frequency	Percent
< 1000	93	30.4
1001- 2000	41	13.4
2001 – 3000	52	17
3001 – 4000	65	21.2
> 4000	55	18
Total	306	100

Occupation of the study subjects		
Occupation	Frequency	Percent
Governmental	75	25.2
Nongovernmental	153	50
House wife	54	17.6
Others	22	7.2
Total	306	100
Regions of study subjects		
Region	Frequency	Percent
Addis Ababa	139	45.4
Oromiya	54	17.6
Amhara	76	24.7
SNNPR	31	10.1
Others	6	2
Total	306	100

As can be seen from the above table, about 45.4% of the study subjects were from Addis Ababa and 24.7%, 17.6%,10.1%, 2% of patients under the study were from Amhara, Oromiya, SNNPR and others respectively. And about 50% of the study subjects were worked in nongovernmental institution and their own private company. The remaining 25.4% were governmental workers, 17.6% were house wife and 2% of study subjects were worked at others working class.

In addition, our chart review of study subject which is filled by phone call interview of study subjects headed marital status indicates that 61.4% of study subjects were married. The remaining study subjects, 31%, 1% and 6.5% were single, divorced and widowed respectively.

6.2. HISTORY OF LIVER DISEASES AND BLOOD TRANSFUSION

Accordingly patient chart review from patient history sheet and I care data base system, it was found that 25(8.2%) of the study subjects under the study had history of liver disease and 281(91.8%) had no any history of liver disease.

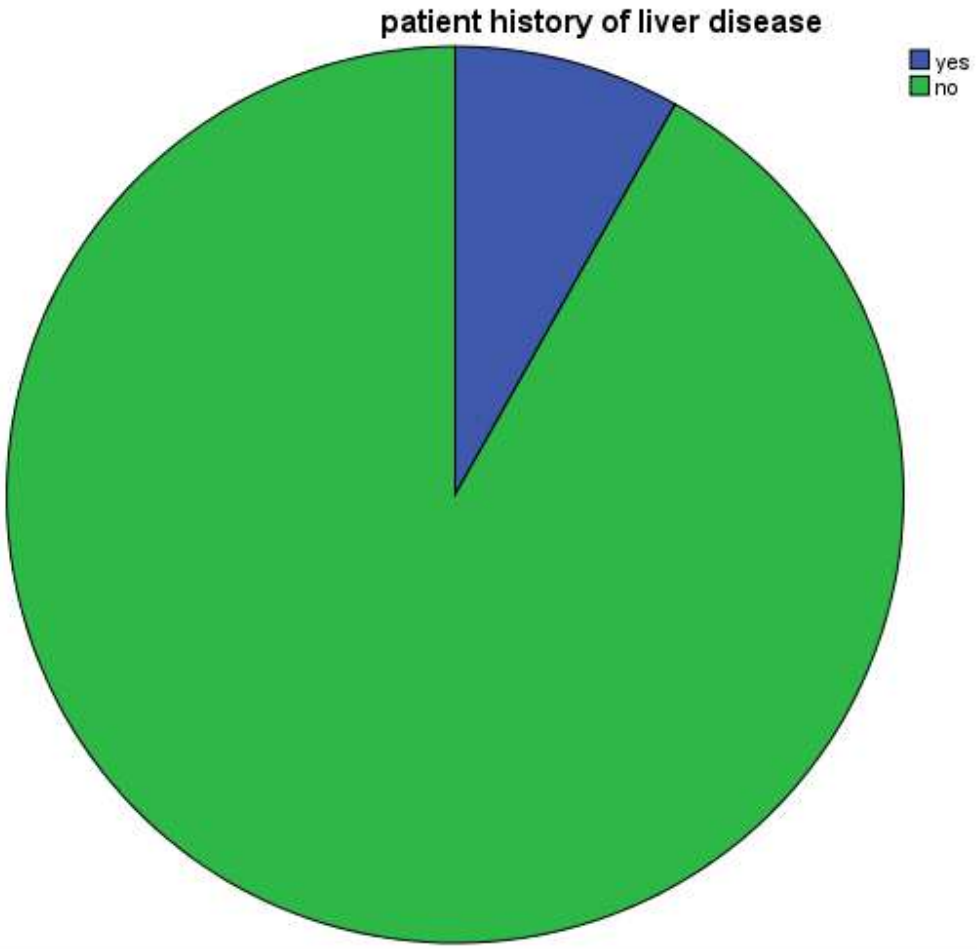

Figure 6.1: Patients history of liver disease of among cardiac patients who had a follow up at cardiac clinic of Tikur Anbessa hospital on November 2020.

Meanwhile this study indicates that among the study subjects about 58(19%) of patients were had a history of blood transfusion. However, their history sheet from their chart and I Care database system suggested that most of the subjects were transfused during their open-heart surgery period. The rest 248(81%) of study subjects were had no history of blood transfusion.

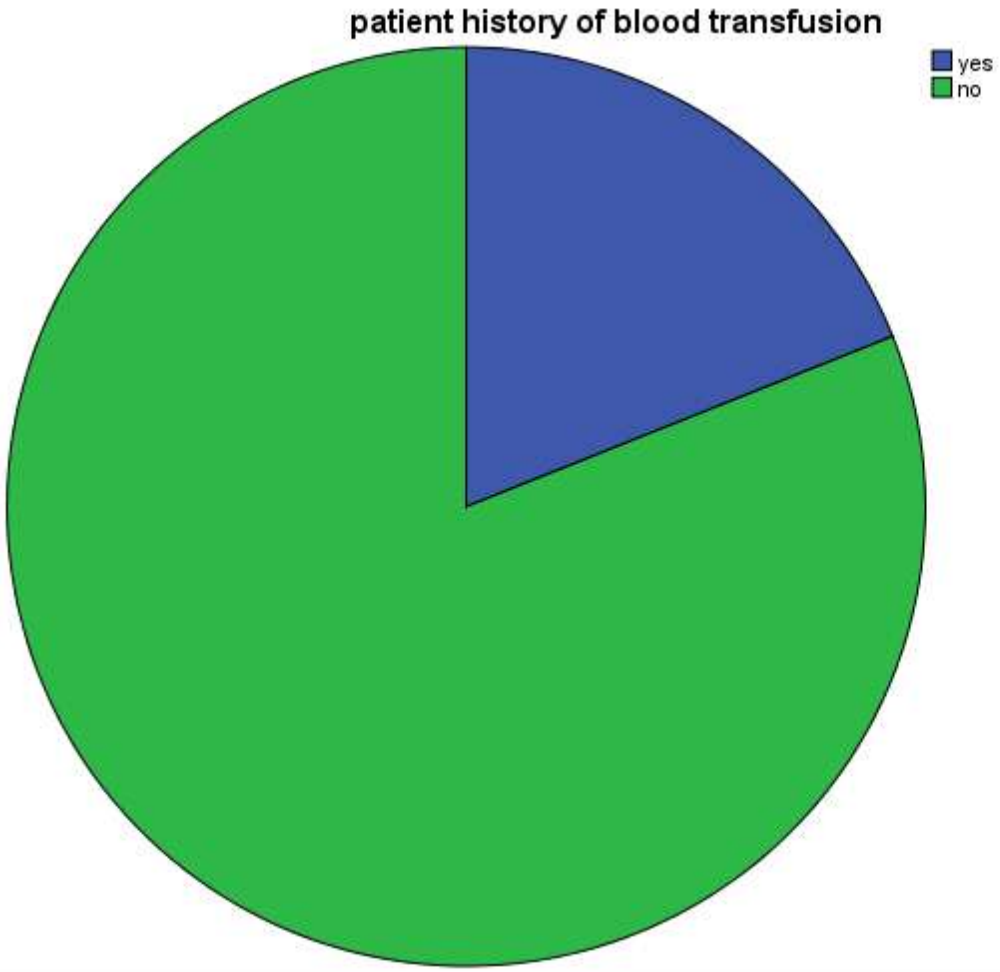

Figure 6.2: Patients history of blood transfusion of among cardiac patients who had a follow up at cardiac clinic of Tikur Anbessa hospital on November 2020.

6.3. CARDIAC DISEASE CONDITIONS

From this study, it was possible to extract most of study subjects had valvular heart disease i.e.181 (59.2%).however IHD accounts (15.7%) and study subjects who had both hypertension and IHD accounts 12.4% while cardiomyopathy shared 5.2% of study subjects. In addition, some of study subjects had more than two and above cardiac disease.

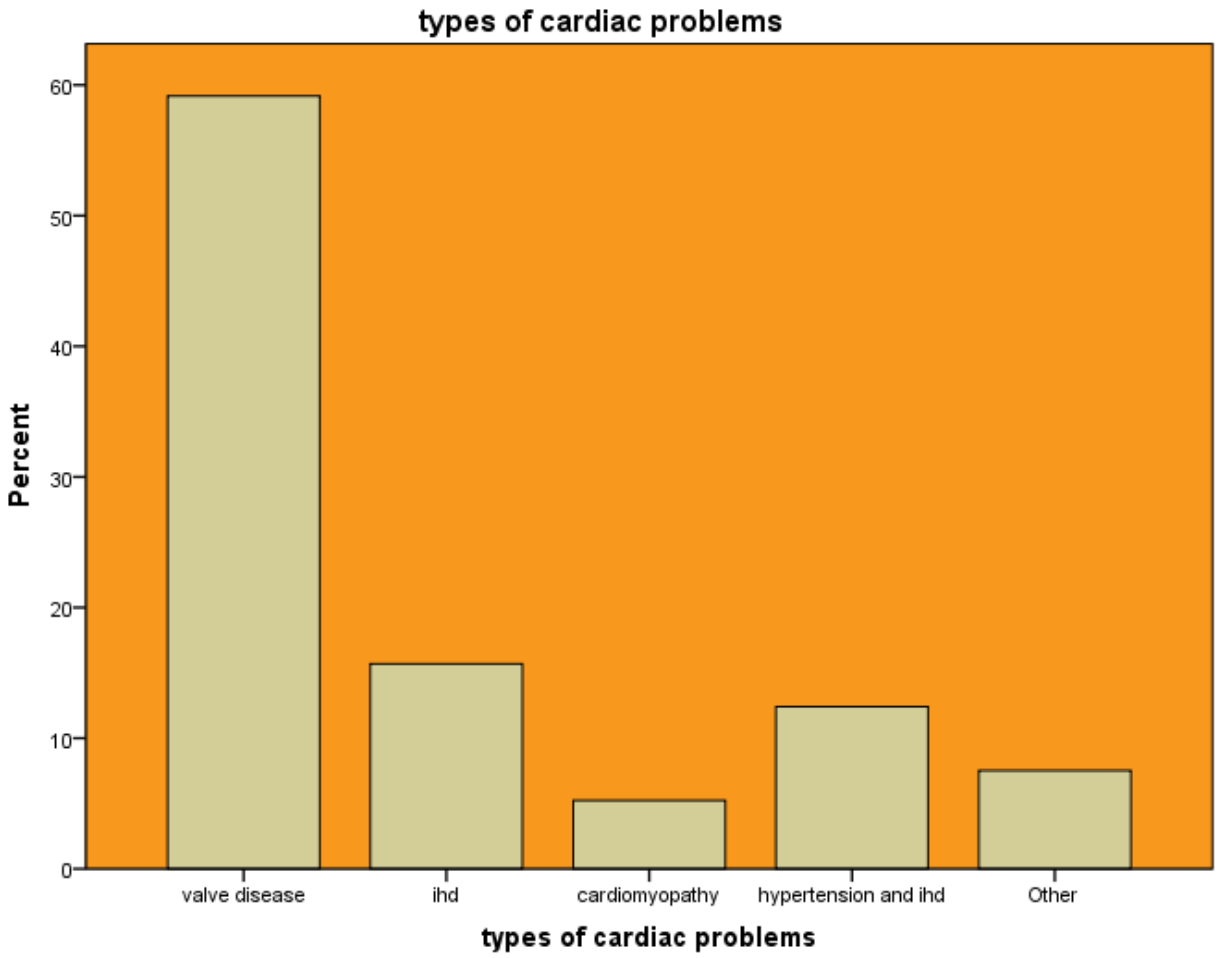

Figure 6.3; Types of cardiac problems among cardiac patients who had a follow up at cardiac clinic of Tikur Anbessa hospital on November 2020.

According to this study, about 262 (86.4%) of the population under the study had no history of open heart surgery using CPB machine and the rest 44 (14.4%) had a history of open heart surgery using heart lung machine. while as our chart review showed that most of them had single or double valve replacement.

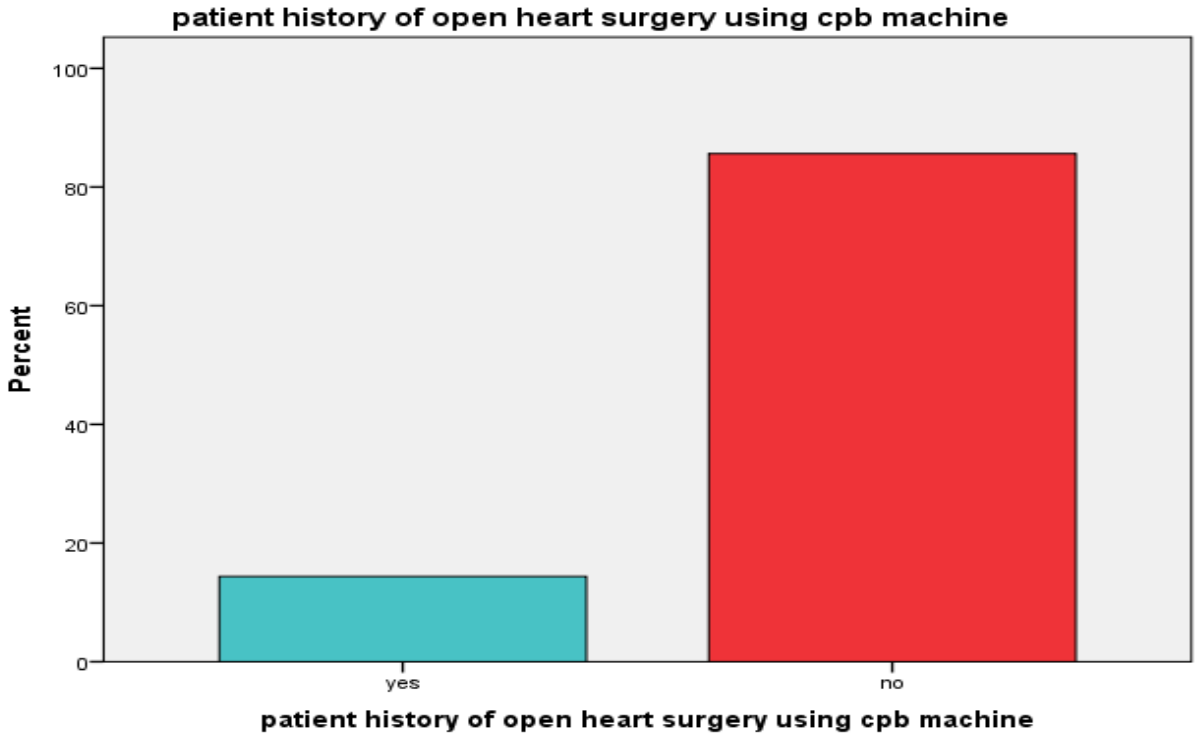

Figure 6.4: Patient history of open-heart surgery among cardiac patients who had a follow up at cardiac clinic of Tikur Anbessa hospital on November 2020.

6.4. USES OF ANTICOAGULANTS

The result showed that most of the patients under the study were used oral anticoagulants. About 291(95.1%) of study subjects used one or more anticoagulants. The rest 4.9% of patients under the study were not used any anticoagulant medication.

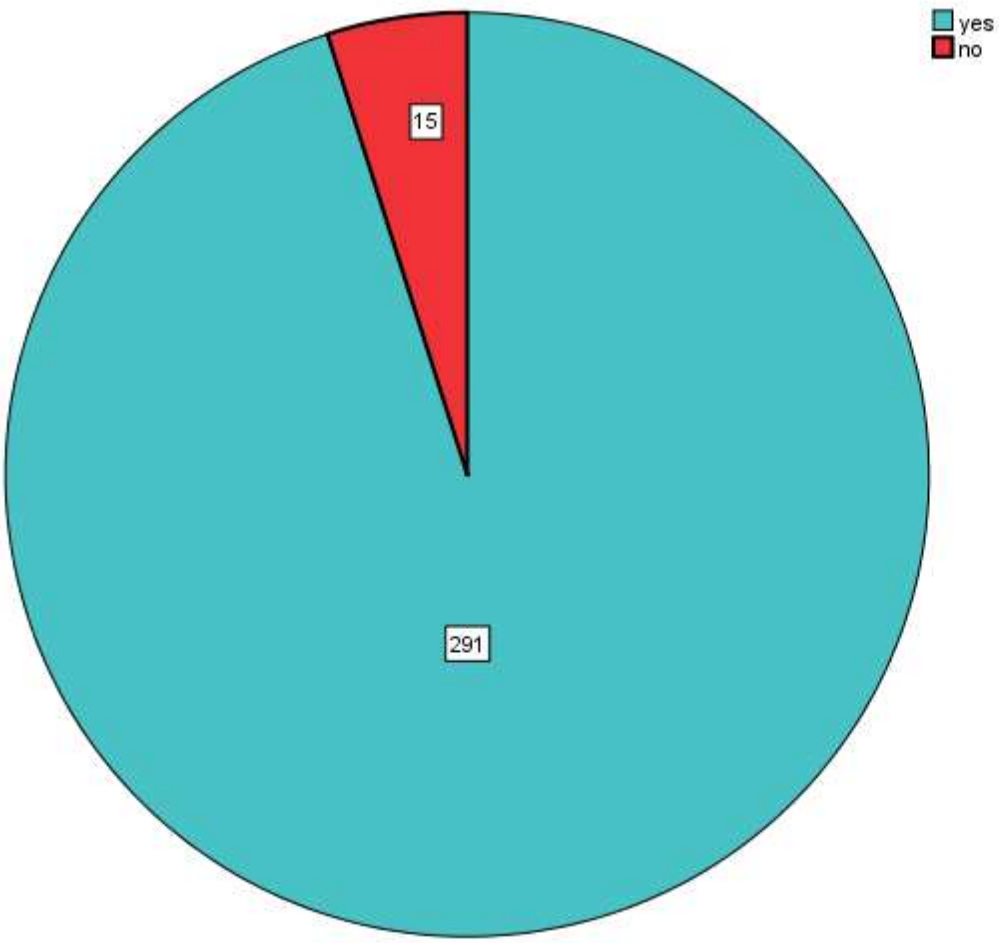

Figure 6.5: Patient history of anticoagulant use among cardiac patients who had a follow up at cardiac clinic of Tikur Anbessa hospital on November 2020.

From the user of anticoagulants about 177(60.8%) of study subjects were used warfarin and 15.8% of study subjects were used aspirin. the remaining study subjects were used two or more anticoagulants at once.

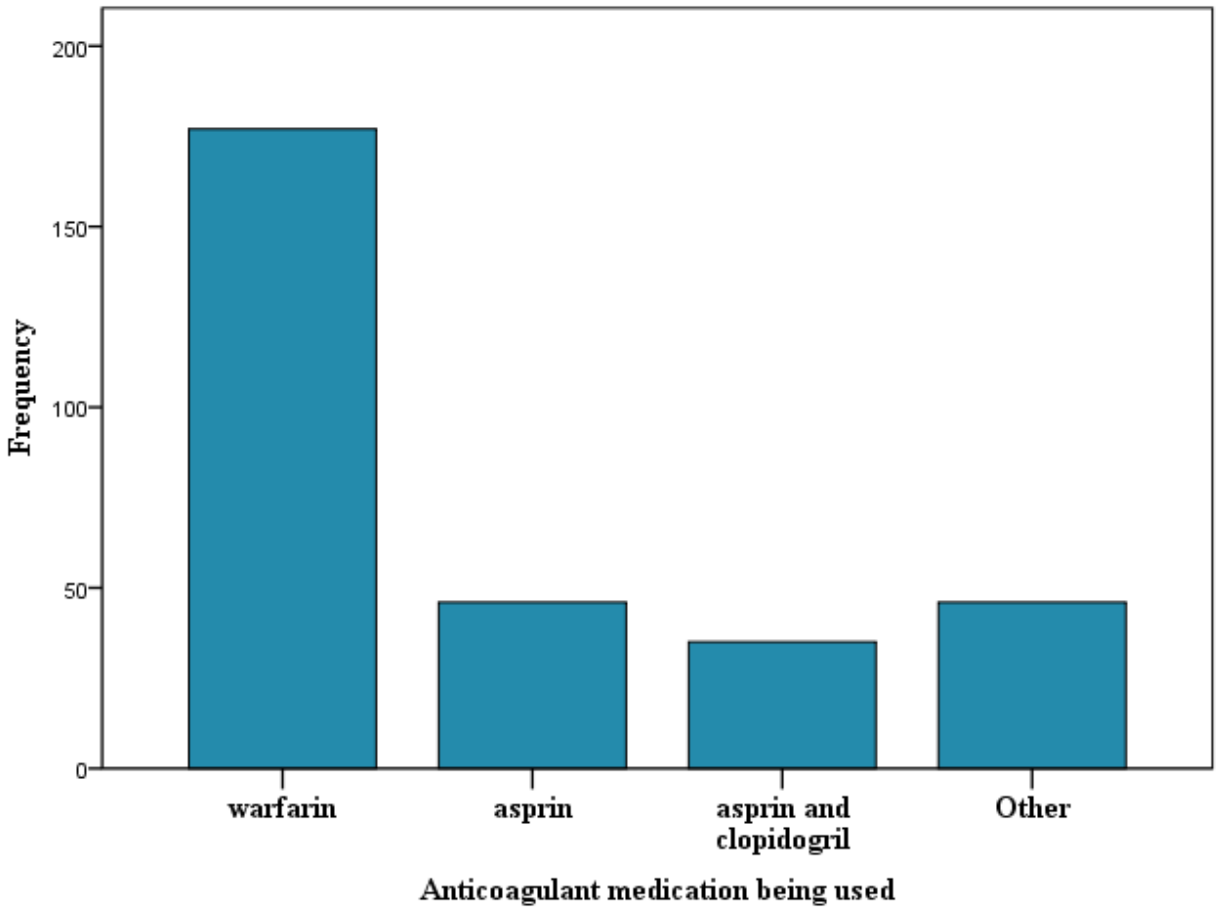

Figure 6.6: Patient history of medication being used among cardiac patients who had a follow up at cardiac clinic of Tikur Anbessa hospital on November 2020.

6.5. PATIENT COAGULATION PROFILES

In this study we found that the mean INR value of a patient under study was 3.037 (SD: ±1.43) and the median was 2.9.While the quarantines was 2.0 – 3.65.

According to our study, the data confirmed that the mean platelet count of the study unit was 282248(SD: ±89589). However, the mean PTT value of patients was 41.7 seconds (SD: ±11seconds). While the minimum PTT was 22 seconds and the maximum was 77 seconds.

Table 6.2: Patients coagulation status

Test item	Mean	Standard deviation	Median	Quarantines	Minimum	Maximum
INR	3.037	±1.43	2.9	2.0 – 3.65	0.47	9.20
PTT	41.7 seconds	±11 seconds	39.3 seconds	35.15-48.2 seconds	22 seconds	77 Seconds
Platelet count	282248	±89589/mm^3	274500/mm^3	214750-350500/mm^3	110000/mm^3	845000/mm^3

6.5. DISCUSSION

This study was carried out to assess the coagulation profiles adult cardiac outpatient departments of Tikur Anbessa hospital which could be baseline for others study related to this topic.

The finding of this study would not represent the coagulation profile of all cardiac patients visiting the hospital as cardiac patients with co-morbid diabetes mellitus were followed at the diabetic clinic and the hospital lacks diagnostic facilities such as cardiac markers and coagulation testes. The study was undertaken with such limitations.

So according to this study, the data confirmed that the mean platelet count of the study unit was 282248mm^3(SD: ±89589mm^3). Which is lower than the study conducted in America, medical university of South Carolina, on Identification of Patients at Risk for Excessive Blood Loss During Coronary Artery Bypass Surgeryi.e. the preoperative platelet count (**mean510×$10^{3,}$ SD:±82000mm^3**). However, the mean PTT value of patients was 41.7 seconds (SD: ±11seconds). This is higher than the study previously used. That is (**the mean PTT was 26.4 SD: ± 5 seconds**). [25]

In this study we found that the mean INR value of a patient under study was 3.037 (SD: ±1.43) and the median was 2.9.While the quarantines was 2.0 – 3.65. This is slightly higher than the study conducted in Cardiff Britain, on Evaluation of the pattern of treatment, level of anticoagulation control, and outcome of treatment with warfarin in patients with non-valvar atrial fibrillation (**Mean 2.5 SD: ± 0.69**), Lower quartile 2.1, Upper quartile 2.8, Median 2.4. [26] Which might be some of the study subjects in our study were used extra anticoagulants in combination with warfarin.

Therefore it is not surprising that preoperative bleeding time and platelet count were significantly associated with subsequent intraoperative blood loss in the present report, because impaired platelet function and decreased platelet number may be primarily responsible for excessive blood loss related to the hemostatic process following CPB. (27)

Although none of the standard coagulation parameters alone were an adequate predictor of subsequent blood loss, bleeding time, platelet count, and PT were, however, significant

contributory variables to the blood loss model, and appear to be related to and directly influence total blood loss for the surgical procedure. Though this study could be a starting point to give attention on the investigation of patient coagulation profile prior to any surgical procedures.

The leading four cardiac disease etiologies identified in this study were RHD, IHD, Hypertension and cardiomyopathy. The finding is similar as compared with the result of other studies done in Ethiopia. [28]

7. RECOMMENDATIONS AND CONCLUSION

7.1. RECOMMENDATIONS

By using our study as reference point we would like to give the following recommendation;

For clinicians : clinicians should have focus on patient coagulation status strictly prior to any surgical procedure especially on patients who takes anti-coagulants and should obtained a detail patient history that makes a sense for any investigation.

For hospital administrator; hospital administrator should give attention on patient data system management and should revised currently used data documentation and entry systems. And the hospital also should deliver important coagulation testes that were not available currently in our hospital like; PT, APTT, TT testes.

Researcher: by using this study as reference other researcher should do further study on this area and as this study is hospital based with limited representativeness population based studies are recommended.

7.2. CONCLUSION

Our study showed that most of the study subjects were used anti-coagulants and their mean coagulation profiles (INR, PTT) were high from the normal range. While this study was carried out to assess the coagulation profiles of adult cardiac outpatient departments of Tikur Anbessa hospital which could be baseline for others study related to this topic. Though as this study is hospital based with limited representativeness further studies are recommended.

Additionally this study would not represent the coagulation profile of all cardiac patients visiting the hospital as cardiac patients with co-morbid diabetes mellitus were followed at the diabetic clinic and the hospital lacks diagnostic facilities such as cardiac markers and coagulation testes. The study was undertaken with such limitations.

8. REFERENCES

1. Curry AN, Pierce JT. Conventional and near‐patient tests of coagulation. Contin Crit Educ AnaesthCare Pain 2007; 7:45‐50.

2. Adhikary SD, Jacob P. Peri‐operative clinical tests of haemostasis and their implications Indian J Anaesth 2005; 49:12‐6.

3. Van Veen JJ, Spahn DR, Makris M. Routine preoperative coagulation tests: An outdated practice? Br J Anaesth 2011; 106:1‐3.

4. Holbrook A, Schulman S, Witt DM, et al. Evidence-based management of anticoagulant therapy: Antithrombotic Therapy and Prevention of Thrombosis,9th ed: American College of Chest Physicians Evidence-Based Clinical Practice Guidelines. Chest 2012; 141(2 Suppl):e152S 84S.

5. Hylek EM, Go AS, Chang Y, et al. Effect of intensity of oral anticoagulation on stroke severity and mortality in atrial fibrillation. N Engl J Med 2003; 349:1019–26.

6. Garcia DA, Baglin TP, and Weitz JI, et al. Parenteral anticoagulants: Antithrombotic Therapy and Prevention of Thrombosis, 9th Ed: American College of Chest Physicians Evidence-Based Clinical Practice Guidelines. Chest 2012; 141(2 Suppl): e24S–43S.

7. Ageno W, Gallus AS, Wittkowsky A, et al. Oral anticoagulant therapy: Antithrombotic Therapy and Prevention of Thrombosis, 9th ed: American College of Chest Physicians Evidence-Based Clinical Practice Guidelines. Chest 2012; 141 (2 Suppl):e44S–88S.

8. Desborough MJ Keeling DM.How to interpret a prolonged prothrombin time or activated partialthromboplastin time. Br J Hosp Med (Lond) 2013; 74:

9. Practice guidelines for perioperative blood transfusion and adjuvant therapies: an updated report by the American Society of Anesthesiologists Task Force on Perioperative Blood Transfusion and Adjuvant Therapies. Anesthesiology 2006; 105: 198–208.

10. Harmening DM, Bethal M. Coagulation Methods in Clinical Hematology and Fundamental of Hemostasis.5th ed. Philadelphia. PA. USA: F.A. Davis Co.; 2009. p. 849‐81.

11.Establishing Reference Ranges and Normal Values for Coagulation Screening in Healthy Indian Male Volunteers Enrolled for a Longitudinal Study;2019

12. van Veen JJ, Spahn DR, Makris M. Routine preoperativecoagulation tests: An outdated practice? Br J Anaesth2011; 106:1‐3.

13. Wahlberg T, Blombäck M, Hall P, Axelsson G. Application ofindicators, predictors and diagnostic indices in coagulationdisorders. I. Evaluation of self-administered questionnairewith binary questions. Methods INF Med 1980; 19:194‐200.

14. Eika C, Havig O, GodalHC.The value of preoperativehaemostatic screening. Scand J Haematol 1978; 21:349‐54.

15. Smetana GW, Macpherson DS. The case against routinepreoperative laboratory testing. Med Clin North Am 2003; 87:7‐40.

16. Chee YL, Crawford JC, Watson HG, Greaves M. Guidelines on the assessment of bleeding risk prior to surgery or invasive procedures. British Committee for Standards in Haematology. Br J Haematol 2008; 140:496‐504.

17. Danielson D, Bjork K, Card R, Foreman J, Harper C, Roemer R, *et al*. Preoperative evaluation. InstClinSystImprov 2012; 10:1‐61.

18. Pirmohamed M, James S, Meakin S, et al. Adverse drug reactions as cause of admission to hospital: prospective analysis of 18 820 patients. BMJ 2004; 329:15–19.

19. Budnitz DS, Lovegrove MC, Shehab N, et al. Emergency hospitalizations for adverse drug events in older Americans. N Engl J Med 2011; 365:2002–12.

20. Staudinger T, Locker G J, Frass M. Management of acquired coagulation disorders in emergency and intensive-care medicine. SemThrombHemost.(1996); 22:93–104. [PubMed]

21. Mei C T, Feeley T W. Coagulopathies and the intensive care setting. IntAnesthesiol Clinics.(1993); 31:97–117. [PubMed]

22.Nuttall G A, Oliver W C, Beynen F M, Santrach P J, Strickland R A, Murray M J. Determination of normal versus abnormal activated partial thromboplastin time and prothrombin time after cardiopulmonary bypass. J CardiothorVascAnesth.(1995); 9:355–361. [PubMed]

23. Addis Ababa health bearue 2004 annual conference report.

24. Twelve-month Outcomes and Predictors of Very Stable INR Control in Prevalent Warfarin Users.

25. Identification of Patients at Risk for Excessive Blood Loss During Coronary Artery Bypass Surgery.

26. Evaluation of the pattern of treatment, level of anticoagulation control, and outcome of treatment with warfarin in patients with non-valvar atrial fibrillation.

27.Bachmann F, McKenna R, Cole ER, Najafi H. The hemostatic mechanism after open-heart surgery. I.. J ThoracCardiovascSurg**1975; 70:7&85.**

28. Patterns of cardiac disease among cardiac patients among cardiac clinic of Jimma university hospital.

CHECKLIST QUESTIONNAIRES

Name of data collector: ----------

Study identification number: ---------- Date: ----------

Part I. Socio-demographic data		
No.	Question	Alternatives(Coding Category)
1 .1	Age	Years……
1.2	Sex	1 Male 2 Female
1.3	Marital status	1.Single 2.Married 3.Divorced 4. Widowed
1.4	Income	1 < 1000 2 1000-2000 3 2001-3000 4 3001-4000 5 >4000
1.5	Occupation	1 Government 2 Non government 3 house wife 4 Others

1.6	Region	1 Addis Ababa 2 Oromia 3 Amhara 4 SNNPR 5 Others
Part II. History of liver diseases and blood transfusion		
2.1	History of known liver disease?	1 Yes 2 No
2.2	Patient historyof blood transfusion?	1 Yes 2 No
Part III. Cardiac disease conditions		
3.1	Types of cardiac problems	1 hypertension 2 valve disease 3 IHD 4 Cardiomyopathy 5 others
3.3	History of open heart surgery using CPB machine	1 yes 2 No

Part IV. Uses of anticoagulants		
4.1	Uses of anticoagulant medication?	1 Yes 2 No
4.2	Anticoagulation medication being used	1 warfarin 2 heparin 3 asprin 4 rivaroxiban 5 others

Part V. Patient Coagulation profiles	
Coagulation profiles	Results (parameter)
INR	
PTT	
Platelet count	