ASSESSMENT OF LOW DOSE ASPIRIN USE FOR PREVENTION OF CARDIOVASCULAR DISORDERS AND ASSOCIATED FACTORS AMONG DIABETIC OUT-PATIENTS AT JIMMA MEDICAL CENTER

BY NIGATU ASFAW

(MD, INTERNAL MEDICINE RESIDENT)

A RESEARCH THESIS TO BE SUBMITTED TO THE DEPARTMENT OF INTERNAL MEDICINE, INSTITUTE OF HEALTH, FOR THE PARTIAL FULFILLMENT OF THE REQUIREMENTS FOR SPECIALITY CERTIFICATE IN INTERNAL MEDICINE

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Approved by

Name	Signature	Date
_____	_____	_____
_____	_____	_____

Declaration

I the under-signed ,declare that this is my original work and has not been presented for seeking a degree in this way in any university and that all resources or the material used for this thesis have dully acknowledged.

	Signature	Date
Nigatu Asfaw Regassa (MD)	_____	_____

The work has been done under the supervision of

Name	Signature	Date
1. Dr. Kedir Negesso (Internist, assistant prof)	_____	_____
2. Mr. Habtamu Abebe (MPHE)	_____	_____

Abstract

Background: Cardiovascular diseases are the most common causes of mortality and morbidity among diabetic patients. Aspirin is recommended for primary and secondary prevention of cardiovascular events in diabetic patients who are eligible for therapy based on active international guidelines. However, these active guidelines are underutilized in these patients.

Objective: To assess low dose aspirin use and associated factors among diabetic patients on follow-up at the diabetes clinic of Jimma Medical Center.

Method: A cross-sectional study was conducted among 387 diabetic patients on follow-up at the diabetes clinic of Jimma Medical Center from October 1, 2020-November 15, 2020. The collected data were cleaned, entered into EpiData version 4.6 and was analyzed using STATA version 16.0. Descriptive statistics and multivariable logistic regression was employed to identify the relationship between dependent and independent variables.

Result: Out of the total (387) diabetic patients interviewed 35.8% of them were 50-64 years old. About half (48.7%) of them had a history of hypertension and 30.1% of them had a history of dyslipidemia. A large proportion (47.2%) of the participants was utilizing a low dose aspirin. Among the patients on low dose aspirin, 41.9% of clients are taking aspirin without an indication for primary prevention, while 25.9% of diabetic patients having an indication to use aspirin were not using as per active guideline. Diabetic patients who live with DM for 2-4 years duration [AOR 3.95 (95% C.I. 1.59, 9.82)], those who live 5-9 years [AOR 5.72 (95% C.I 3.04, 8.09)], 10-14 years [AOR 6.25 (95% C.I. 2.33, 16.75)], and 15 years and above years [AOR 3.49 (95% C.I. 1.30, 9.35)], as compared to less than 2 years. Those in the age group of 40-49 years, 50-64 years, and 65 years above were 3.99, 7.28, and 8.51 more likely to utilize a low dose of aspirin as compared to those under 30 years age. Participants who have a history of hypertension [AOR 1.97 (95% C.I 1.11, 3.50)] and those who have dyslipidemia [AOR 3.07 (95% C.I 1.60, 5.90)] are more likely to utilize a low dose of ASA compared to their counterparts.

Conclusion: A high proportion of DM patients on follow-up were using a low dose aspirin without indications as per active guidelines. Duration of diabetes, age, having hypertension and dyslipidemia were significant factors influencing use of low dose aspirin Therefore, health workers shall follow these guidelines for use of low dose aspirin for primary and secondary prevention. Even though further studies on determinants of low dose of aspirin use and its consequences on longitudinal base is needed, appropriate information, education, and communication shall be disseminated for diabetic patients to increase awareness on the use of aspirin.

Keywords*: - A*spirin utilization, Diabetes, Cardiovascular diseases

Acknowledgement

Most of all, I would like to pay my deepest gratitude to my advisors, Dr. Kedir Negesso, and Mr. Habtamu for their support and provision of guidance in developing this research thesis. I also thank the research office for giving me this chance to undertake this thesis. I am also grateful to my colleagues who provided me with supportive ideas. Last but not least I would like to acknowledge Jimma Medical Center Outpatient teams for their unreserved cooperation to undertake this thesis.

Table of Contents

List of tables and figures

List of abbreviations and acronyms

ACC	American College of Cardiology
ADA	American diabetes association
AHA	American Heart Association
ASA	Acetylsalicylic acid, Aspirin
ASCVD	Athero-sclerotic cardio-vascular disease
CHD	Coronary heart disease
CV	Cardio- Vascular
CVD	Cardiovascular disease
DM	Diabetes Mellitus
FBS	Fasting blood sugar
MI	Myocardial infarction
JMC	Jimma medical center
UR	Uncertainty range
US	United States
WHO	World health organization

1. Introduction

1.1. Background

The burden of cardiovascular disease (CVD) is substantial in patients with diabetes mellitus, who have a two-to four-fold increase in the incidence of cardiovascular events compared with age- and sex-matched, non-diabetic persons(1).

The prevalence of DM increased from 108 million (4.7%) in 1980 to 425 million (8.5%) in 2017, and it is estimated to be 629 million by 2045 (2). Morbidity and mortality of cardiovascular disease in diabetes mellitus patients with type 2 DM have a risk of death from cardiovascular causes that is two to six times that among persons without DM, and among white Americans the age-adjusted prevalence of coronary heart disease is twice as high among those with type 2 DM as among those without DM (3).

Diabetes-related cardiovascular disease complications are considered to be rare in Africa but are on the rise and are regularly associated with classic cardiovascular risk factors. Coronary heart disease may affect 5% to 8% of type 2 diabetic patients and cardiomyopathy, up to 50% of all patients. Close to 15% of patients with stroke have diabetes, and up to 5% of diabetic patients present with cerebrovascular accidents at diagnosis. Peripheral vascular disease prevalence varies across sites from 4% to 28% (4).

In 2015, the Ethiopian Diabetes Association (1.33 million) and IDF (1.30 million) reported almost the same number of people living with diabetes in the country (5). A study with urban and rural sampled populations in the Southern region estimated the prevalence of diabetes mellitus (type 1 and 2) to be 4.9% among adults aged 18 years and above. The second study, with urban sampled population in the Oromia region, estimated the prevalence of type 2 diabetes mellitus to be 5.3% among adults aged 40 years and above. Two studies on the hospital-based prevalence of diabetes were found. In these studies, the prevalence of diabetes was estimated to be 0.5% in all age-groups and 1.2% among patients aged 20 years and above (6).

In the primary prevention trials, aspirin allocation yielded a 12% proportional reduction in serious vascular events (7). Aspirin has been shown to be effective in reducing cardiovascular morbidity and mortality in high-risk patients with previous MI or stroke (secondary prevention). Its net benefit in primary prevention among patients with no previous cardiovascular events is more controversial both for patients with diabetes and for patients without diabetes (8).

Aspirin therapy (75–162 mg/day) may be considered as a primary prevention strategy in those with Type 1 or Type 2 diabetes who are at increased cardiovascular risk. This includes most men and women with diabetes aged 50 years who have at least one additional major risk factor (family history of premature atherosclerotic cardiovascular disease, hypertension, dyslipidemia, smoking, or albuminuria) and are not at increased risk of bleeding (8).

An association between increases in aspirin dose and risk of adverse events has been confirmed in multiple studies, whereas no such dose relationship has been identified for efficacy. This suggests that following the rapid, acute inhibition of platelet COX-1 with 160 to 325 mg of aspirin, every effort should be made to minimize the long-term dosage (9).

1.2. Statement of the Problem

In 2008, of the 57 million deaths that occurred globally, 36 million of these due to non-communicable diseases (NCDs), of which CVD and cancer were responsible for 17 million (47 % of all NCD deaths) and 7.6 million (21 % of all NCD deaths), respectively (10).

Cardiovascular disease is the leading cause of mortality in the United States of America. In the year 2010, it is responsible for more than 800,000 deaths which are nearly 30 % of the total deaths recorded in that particular year (11). It is also the leading cause of death for people of most racial/ethnic groups, with an estimated cost of >$200 billion annually in healthcare services, medications, and lost productivity. Much of this is attributable to a suboptimal implementation of prevention strategies and uncontrolled ASCVD risk factors in many adults (10).

World Health Organization (WHO) estimated in 2011 that 34% of the Ethiopian population is dying from non-communicable diseases, with a national cardiovascular disease prevalence of 15%, cancer and chronic obstructive pulmonary disease prevalence of 4% each, and diabetes mellitus prevalence of 2% (6).

The burden of cardiovascular disease (CVD) among patients with diabetes is substantial. Individuals with diabetes are at 2- to 4-fold increased risk of cardiovascular events compared with age- and sex-matched individuals without diabetes. In diabetic patients over the age of 65 years, 68% of deaths are from coronary heart disease (CHD) and 16% are from stroke (12).

The prevalence of antiplatelet use in the USA was 54% overall; 45% for subjects without known CVD vs. 78% for those with CVD; 46% for women vs. 63% for men; and 45% for younger subjects (age< 65) vs. 62% for senior citizens (13). An estimated 27% of adults with diabetes had CVD, and an additional 71% had one or more CVD risk factors. Aspirin was used regularly by 37% of those with CVD and by 13% of those with risk factors only (13).

Despite the beneficial effects of aspirin in primary and secondary prevention of cardiovascular disease, it is under-utilized (14) .There is limited data regarding the utilization of aspirin for primary and secondary prevention of cardiovascular events in diabetic patients in Ethiopia. This paper may be used as input in assessing the use of aspirin in diabetic patients.

2. Literature Review

2.1. Literature review

2.1.1 Prevalence of low dose aspirin use

In the ASCEND trial, A total of 15,480 participants underwent randomization. During a mean follow-up of 7.4 years, serious vascular events occurred in a significantly lower percentage of participants in the aspirin group than in the placebo group. In contrast, major bleeding events occurred in the aspirin group, as compared with in the placebo group with most of the excess being gastrointestinal bleeding and another extracranial bleeding (15).

In the Analysis of the national health and nutrition examination survey 2011–2012 to examine the use of aspirin for CVD prevention United states of America patients without previously diagnosed CVD were classified into high and low risk based on their Framingham Risk Score (10-year coronary heart disease risk). Among patients without previously diagnosed CVD, 22.5% were classified as high risk. Of the high-risk individuals, 40.9% reported being told by their physician to take aspirin, with 79.0% complying. Among those who were at low risk, 26.0% were told by their physician to take aspirin, with 76.5% complying (16).

To ascertain whether recommendations for the use of Statins and Aspirin as primary prevention in diabetic patients are correctly implemented at the institution cross-sectional study was conducted between February 2014 and April 2014 at the General Practice Department of King Abdul-Aziz University Hospital. Three hundred twelve patients were included in the study. Data were collected from the electronic patient medical records for the characteristics of the patients, existing co-morbidities, and results of laboratory investigations. Descriptive statistics were performed for all variables. Of 312 patients, aspirin was indicated for 17.0% but it was not prescribed. It was both indicated and prescribed in 36.2% of the cases (1).

To examine the frequency and practice-level variation in inappropriate aspirin use for primary prevention in a large U.S. nationwide registry, the national Cardiovascular Disease registry's Practice Innovation and Clinical Excellence registry, of USA assessed 68,808 unique patients receiving aspirin for primary prevention from 119 U.S. practices. The frequency of inappropriate aspirin use was determined for primary prevention (aspirin use in those with 10-year CVD risk <6%). Inappropriate aspirin use frequency was 11.6% in the overall cohort. There was significant practice-level variation in inappropriate use. More than 1 in 10 patients in this national registry were receiving inappropriate aspirin therapy for primary prevention, with significant practice-level variations (17).

The prevalence of antiplatelet use was the USA 54% overall; 45% for subjects without known CVD vs. 78% for those with CVD; 46% for women vs. 63% for men; and 45% for younger subjects (age< 65) vs. 62% for senior citizens. After controlling for race/ethnicity, income, education, marital status, insurance status, and prescription coverage, the following were associated with the use of antiplatelet therapy: the presence of known CVD, male sex and age >

= 65. The prevalence of antiplatelet therapy for younger women without CVD was 32.8% compared to a prevalence of 90.3% for older men with CVD (13).

In the ACCEPT-D trial, Aspirin has been shown to reduce major cardiovascular events by about one quarter in a wide range of high-risk populations (9).

2.1.2. Factors associated with low dose aspirin use

Evidence in support of aspirin prophylaxis is conflicting, though some meta-analyses have underlined potential benefits in reducing cardiovascular events. Despite this apparent benefit, bleeding risk with aspirin is consistently higher versus control and remains a concern (18).

A multidisciplinary expert panel (blinded to treatment assignments) adjudicated study outcomes in both the aspirin and no aspirin groups, 56 fatal events occurred. Patients with an occurrence of nonfatal stroke totaled 114 in the aspirin group and 108 in the no aspirin group; of non-fatal myocardial infarction, 20 in the aspirin group and 38 in the no aspirin group; of undefined cerebrovascular events, 3 in the aspirin group and 5 in the no aspirin group. Aspirin significantly reduced the incidence of nonfatal myocardial infarction transient ischemic attack and significantly increased the risk of extracranial hemorrhage requiring transfusion or hospitalization (19).

In the study entitled with Aspirin, Statins, or Both Drugs for the Primary Prevention of Coronary Heart Disease Events in Men: A Cost-Utility Analysis For 45-year-old men who do not smoke, are not hypertensive, and have a 10-year risk for CHD of 7.5%, aspirin was more effective and less costly than no treatment (20).

In the study entitled with Adherence to therapies for secondary prevention of cardiovascular disease: a focus on aspirin Reasons for poor adherence or no adherence may be related to the treatment itself: its ease of use or lack thereof, frequency of dosing, or adverse effects. Patient-specific factors, such as age, mental health, or other existing medical conditions (and socioeconomic factors (i.e., education level, health literacy, access to social support) can also influence patient compliance. Lastly, healthcare system-related factors, such as lack of continuity of care, inadequate patient education, or poor doctor-patient relationships, can negatively impact adherence to medication. In patients taking chronic therapy for CVD, the frequency of dosing was inversely related to adherence: the higher the dosing frequency, the lower the patient adherence is the pill burden**.** (21)**.**

2.1.3. Social and demographic variables

Analysis of the national health and nutrition examination survey in the united states of America 2011–2012 to examine the use of aspirin for CVD prevention, the result of this study indicated that age, access to a regular source of care, education, and insurance status were significant predictors of patient-reported physician recommendations for aspirin use for primary prevention.

Among high-risk patients, age, race, and insurance status were significant predictors of reported recommendations for aspirin use. Among low-risk patients, age, education, obesity, and insurance status were significant predictors of reported recommendations for aspirin use (16).

To assess Diabetes as a risk factor for incident coronary heart disease in women compared with men: a systematic review and meta-analysis of 64 cohorts including 858,507 individuals and 28,203 coronary events. The RR for incident CHD associated with diabetes compared with no diabetes was 2.82 in women and 2.16 in men. The multiple-adjusted RRR for incident CHD was 44% greater in women with diabetes than in men with diabetes with no significant heterogeneity between studies. Women with diabetes have more than a 40% greater risk of incident CHD compared with men with diabetes (22).

The prevalence of antiplatelet use was 54% overall; 45% for subjects without known CVD vs. 78% for those with CVD; 46% for women vs. 63% for men; and 45% for younger subjects (age< 65) vs. 62% for senior citizens. After controlling for race/ethnicity, income, education, marital status, insurance status, and prescription coverage, the following were associated with the use of antiplatelet therapy: the presence of known CVD, male sex, and age > = 65. The prevalence of antiplatelet therapy for younger women without CVD was 32.8% compared to a prevalence of 90.3% for older men with CVD (13).

In 2011–2012, one-third of U.S. adults aged above 40 years reported taking preventive aspirin and/or other antiplatelet medications, 97% of whom indicated preventive aspirin use. Preventive aspirin use increased with age (from 11% of those aged 40–49 years to 54% of those above 80 years of age). Non-Hispanic whites (35%) and black (30%) adults were more likely to take preventive aspirin than non-Hispanic Asians (20 %,) and Hispanic (22 %,) adults. Adults with, compared with those without health insurance, and adults with 2 doctor visits in the past year, diagnosed diabetes, hypertension, or high cholesterol were twice as likely to take preventive aspirin. Among those with cardiovascular disease, 76% reported taking preventive aspirin and/or other antiplatelet medications, of which 91% were taking preventive aspirin. Among adults without cardiovascular disease, 28% reported taking preventive aspirin. Adherence rates to medically recommended aspirin use were 82% overall, 91% for secondary prevention, and 79% for primary prevention (23).

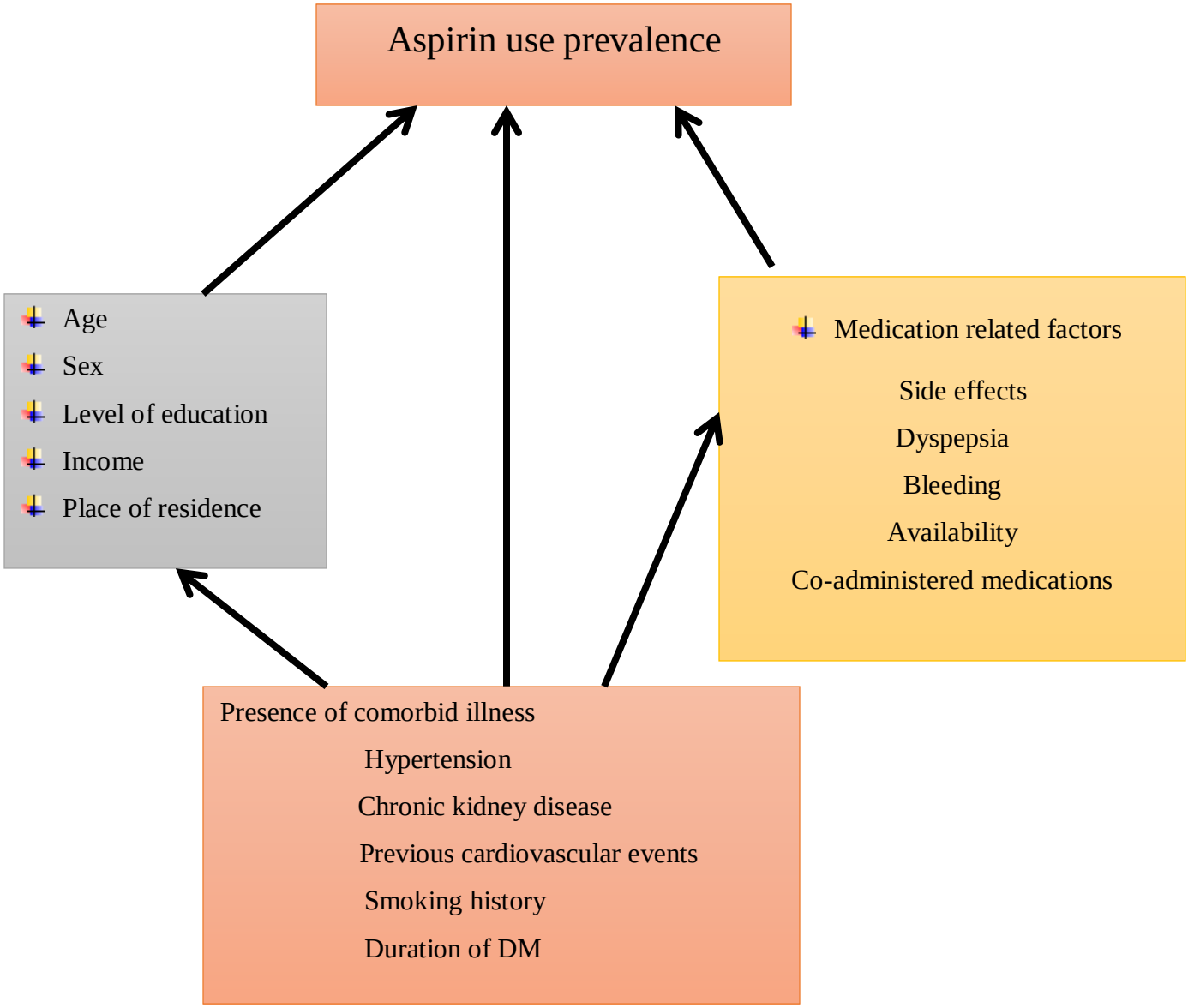
2.1.4 Clinical variables

To examine effects of aspirin on risks of vascular events and cancer according to bodyweight and dose: analysis of individual patient data from randomized trials among ten eligible trials of aspirin in primary prevention (including 117 279 participants), bodyweight varied four-fold, and trial median weight ranged from 60·0 kg to 81·2 kg). The ability of 75–100 mg aspirin to reduce cardiovascular events decreased with increasing weight, with benefits seen in people weighing 50–69 kg but not in those weighing 70 kg or more for vascular death). Furthermore, the case

fatality of a first cardiovascular event was increased by low-dose aspirin in people weighing 70 kg or more) (24).

In the study designed to examine Aspirin resistance in patients with type II diabetes mellitus altogether 41.9% of patients with DM were aspirin non-responders. Aspirin resistance was observed in 43.2% of non-diabetic patients. The presence of diabetes mellitus did not affect aspirin response in the whole study population. Hypercholesterolemia was the only predictor of aspirin resistance in multivariate analysis in diabetic patients. The prevalence of aspirin resistance is comparable in diabetic and non-diabetic patients. Hypercholesterolemia is the only independent predictor of aspirin resistance in diabetic patients (25).

2.1.5 Conceptual framework



2.2 Significance of the study

Prevention of CVD events is important, and understanding physician recommendations for aspirin therapy is critical for delivering quality health care. The current understanding of who is being encouraged to take aspirin for CVD prevention is limited.

The study will fill the gap concerning the shortage of data on the use of aspirin among diabetes patients in southwestern Ethiopia. This study also shows the work being done in the prevention of CVD events in this hospital and unveils what remains to be done in the future. It also serves as bases for further similar studies. Additionally, the treating physicians will be recommended about the patients' current level of treatment in line with the current updated treatment guidelines.

3. Objectives

3.1. General objectives

The general objective of this study is to assess the magnitude of low dose aspirin use and associated factors among diabetic patients on follow up at Jimma Medical Center diabetic clinic, Southwest Ethiopia, in 2020.

3.2. Specific objectives

- To assess the magnitude of low dose aspirin use among diabetics on follows up.
- To assess the pattern of use of low dose aspirin among diabetics on follow up
- To assess the factors associated with inadequate use of aspirin among diabetics.

4. Methods and Materials

4.1. Study area and study period

The study was conducted in the diabetes clinic of JMC, which is located in Jimma zone. Jimma zone comprises Jimma town and its nearby woredas. It is located in South West of Ethiopia, Oromia regional state, with an estimated population of 2,486,155. The town is located 346 KM from the capital, Addis Ababa. Jimma medical center is the only teaching and referral hospital for the southwest population in the country. The hospital gives health services at the inpatient and outpatient levels as a referral Hospital for 15 million populations in the South West of the country. Under the Department of Internal medicine, it has general medical wards, sub-specialty units with a total of 120 beds and chronic follow-up clinics. The diabetes clinic provides services for about 400-500 diabetic patients over a period of a month both from Jimma town and surroundings. Patients are being followed by internists and internal medicine residents.

The study was conducted from October 1, 2020 – November 15, 2020.

4.2 Study design

A cross-sectional study was done.

4.3 Population

4.3.1. Source population:

All diabetic patients on follow up at diabetes clinic of JMC during October 1, 2020 -November 15, 2020.

4.3.2. Study population:

All Type 1 and Type 2 diabetic patients on follow up at diabetes clinic of JMC from October 1, 2020 -November 15, 2020.

4.4. Inclusion and exclusion criteria

4.4.1. Inclusion criteria

All Type 1 and Type 2 diabetic patients on follow up at JMC diabetes clinic.

4.4.2. Exclusion criteria

All patients who deny verbal consent to the interview were excluded.

4.5. Sample size determination and sampling technique

4.5.1. Sample size determination:

The sample size can be determined by

$$N = \left(\frac{z\alpha}{2}\right)^2 p\left(\frac{1-p}{d^2}\right)$$

Where N = sample size $\quad Z\,x/2 = 1.96$

p = prevalence of aspirin uses (50%)

d = marginalized error which is 0.05 (5%)

Confidence interval= 95%

$= 384$

Adding a 5% non-responder rate, the sample size is determined to be 403.

4.5.2 Sampling technique:

A convenient sampling technique was used taking consecutive patients who come for follow up until the sample size is reached within the study period.

4.6 Measurements and study variables

4.6.1 Instrument

A questionnaire was used for data collection with the following contents: age, sex, chart number, marital status, level of education, monthly income, area of residence, duration of DM, history of CVD and co-administered medications.

4.6.2 Study variables

4.6.2.1 Dependent variables

- Low dose aspirin use(yes ,no)

4.6.2.2 Independent variables

- Age
- Sex
- Duration of DM
- Monthly income
- Place of residence
- Level of education
- History of CVD
- Co-administered medications
- Marital status
- Hypertension
- Chronic kidney disease /albuminuria
- Smoking
- Dyslipidaemia
- Side effects(dyspepsia, bleeding)
- Major cardiovascular events

4.7 Operational Definition

- **Diabetes mellitus**: Refers to a group of common chronic metabolic disorders that share the phenotype of hyperglycemia (12).

- **Primary prevention**: Initiating appropriate interventions to decrease the likelihood of the first cardiovascular disease occurrence (8).

- **Secondary prevention**: Initiating the appropriate interventions after a patient suffered an initial cardiovascular insult to minimize the possibility of further insults (8).

- **Dyslipidemia**: Refers to an abnormal serum concentration and /or abnormal modifications of lipids in the body (8).

- **Low dose aspirin**: A dose of aspirin in the range of 75- 162 mg (8).

- **ASCVD score:** Is a score with different components being used to predict the 10 years' likelihood of developing CVD (8).

- **Major Cardiovascular events**: composite of nonfatal stroke, non-fatal myocardial infarction, and cardiovascular death (8).

4.8. Data collection procedure

Data were collected manually using a questionnaire. The data were collected by the investigator. The charts of the study population were collected and reviewed after cross-checking chart number on the chart with that on the registration book. Additionally, patients were also interviewed to get the data not found in the charts. Then the data were filled by the investigator into the questionnaire. Standard and infection based infection prevention protocols were applied in order to prevent COVID 19 transmission.

4.9 Data quality management

All data were collected using a uniform data collection format. All investigators were trained on the standardized study protocol and data collection format before initiation of the study. To ensure data quality, a pre-test was conducted on 5% of the sample; training was given to data collectors and supervisors on the data collection process. The collected data was checked for completeness and consistency on each day of collection. The principal investigator-led the overall activities during the data collection period. Questionnaires were prepared in English and back-translated into Afan Oromo/Amharic and translated back into English to check their consistency. The Afan Oromo /Amharic versions were used for data collection after pretesting on 5% of the actual sample size before the data collection. Amendments were made accordingly after pre-testing.

4.10 Data processing and analysis

Data were entered, coded, and cleaned in EpiData manager version 4.6 and then exported to STATA version 16.0 for analysis. Summary findings were presented by tables. Descriptive statistics were used to determine the demographic characteristics and pattern of aspirin utilization.

The potential predictor variables were tested in bi-variable logistic regression separately for their association with aspirin utilization. The variables which are significant in the bi-variable analysis at a cut point of P-value of < 0.25 were a candidate for multi-variable logistic regression analysis. Finally, a p-value < 0.05 will be used as a cut-off point for the presence of statistical significance.

4.11 Dissemination of result

The findings of the study will be disseminated to all relevant stakeholders like Jimma University, Clinicians, researchers, and others through presentation Seminars and publications. Copies of the research will be given to Jimma University, Faculty of public health postgraduate program, and the Department of Internal Medicine. Publications in peer-reviewed, national or international journals will also be considered.

4.12 Ethical issues

Ethical clearance was obtained from the Ethical Review Committee of Jimma University. Permission was obtained from the hospital. Patient confidentiality was ensured during the study period. There were no risky procedures that were applied to patients.

5. Result

5.1. Socio-demographic characteristics of the study participants

A total of 387 diabetic patients were interviewed for the study, yielding a response rate of 95.3%. Out of the total diabetic patients interviewed 35.8% of them were 50-64 years old, followed by 40-49 years of age, and 19.4% of them were in the age group of 65 years and above. The mean [95% C.I] age of the participants was 48.8[48.2, 51.4] years) As showed in the table 1 below, 85.3% of the participants were married, 42.5% of respondents attended a primary school, 28.6% of them never attended formal education while 14.9% of them attended secondary school.

Table 1: Socio-demographic characteristics of diabetic patients on follow up at Jimma Medical Center diabetic clinic, Southwest Ethiopia, in 2020.

Variables	Categories	Frequency (n=388)	Percentage
Age group (in years)	<=29	55	14.2
	30-39	37	9.5
	40-49	80	20.6
	50-64	139	35.8
	>=65	77	19.8
Sex	Male	268	69.1
	Female	120	30.9
Marital status	Married	331	85.3
	Single	35	9.1
	Divorced	10	2.5
	Widowed	12	3.1
Education	Never attended school	111	28.6
	Primary school	165	42.5
	Secondary school	58	14.9
	College and above	54	13.9
Residence	Urban	179	46.1
	Rural	209	53.9
Monthly Income (in ETB)	<500	17	4.4
	500-1500	61	15.7
	1501-3000	60	15.5
	3001-5000	86	22.2
	>=5001	164	42.3

5.2. Clinical characteristics of the study participants

Of the total participants, 30.9% of them were having 5-9 years history of diabetic mellitus, 23.5% of them were 2-4 years duration and 16.2% for 10-14 years. About half (48.7%) of them had a history of hypertension and 30.1% of them had a history of dyslipidemia. Twenty-two diabetic patients were not assessed for dyslipidemia and chronic kidney disease/albuminuria (Table 2).

Table 2: Clinical characteristics of diabetic patients on follow-up at Jimma Medical Center diabetic clinic, Southwest Ethiopia, in 2020.

Variables	Categories	Frequency (n=388)	Percentage
Duration of DM (in years)	<=1	60	15.5
	2-4	91	23.5
	5-9	120	30.9
	10-14	63	16.2
	>=15	54	13.9
History of hypertension	Yes	189	48.7
	No	199	51.3
Current smoker	Yes	6	1.5
	No	382	98.5
Dyslipidemia (n=366)	Yes	110	30.1
	No	256	69.9
Chronic Kidney disease/albuminuria (n=366)	Yes	27	7.4
	No	339	92.6
History of heart attack, ischemic stroke or peripheral arterial disease	Yes	27	6.9
	No	361	93.1
Type of heart disease (n=27)	Myocardial infarction	7	25.9
	Ischemic stroke	17	62.9
	Peripheral arterial disease	3	11.2

5.3. Magnitude of low dose aspirin use among diabetics on follow up

Large proportion (47.2%) of the study participants reported they have been utilizing low dose of aspirin (figure 1)

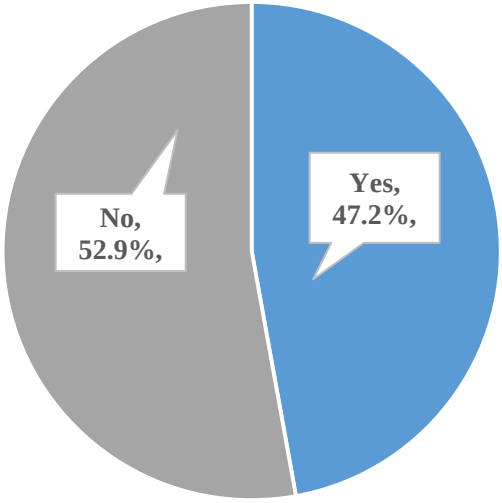


Figure 1: Magnitude of low dose aspirin use among diabetics on follow up

5.4. Reasons for not using low dose aspirin use in indicated cases

Among 17 clients those aspirin is indicated (10 clients for primary and 7 for secondary), the most commonly cited reason for not using low dose aspirin were: being not prescribed (55.2%), dyspepsia (10.3%) and other reasons (34.5%) like availability, COVID-19, medication cost, and bleeding.

5.5. Pattern of use of low dose aspirin among diabetics on follow up

The largest proportions (24.2%) of participants taking low dose ASA were in the age group of 50-64 years old and only 1.0% of 30-39 years age group were the lowest across the age categories. One hundred thirty-nine male participants reported they were taking low dose ASA. Regarding the educational status of the participants, those who attended primary school were more users (18.1%) of low dose ASA than another educational status. Participants with high monthly income status (>=5001 birr) were more users (24.7%) of ASA (Table 3).

Table 3: Pattern of use of low dose aspirin use among diabetics on follow up at Jimma Medical Center diabetic clinic, Southwest Ethiopia, in 2020.

Variables	Categories	Have you been taking low dose ASA	
		YES (%)	NO (%)
Age group (in years)	<=29	5 (1.3)	50 (12.9)
	30-39	4 (1.0)	33 (8.5)
	40-49	24 (6.2)	56 (14.4)
	50-64	94 (24.2)	45 (11.6)
	>=65	56 (14.4)	21 (5.4)
Sex	Male	136 (35.1)	132 (34.0)
	Female	47 (12.1)	73 (18.8)
Education	Never attended school	59 (15.2)	52 (13.4)
	Primary school	71 (18.1)	94 (24.2)
	Secondary school	23 (5.9)	35 (9.0)
	College and above	30 (7.7)	24 (6.2)
Residence	Urban	96 (24.7)	83 (21.4)
	Rural	90 (22.2)	122 (31.4)
Monthly Income (in ETB)	<500	5 (1.3)	12 (3.1)
	500-1500	32 (8.3)	29 (7.5)
	15001-3000	27 (6.9)	33 (8.5)
	3001-5000	51 (13.1)	35 (9.0)
	>=5001	68 (17.5)	96 (24.7)
Duration of DM (in years)	<=1	13 (3.4)	47 (12.1)
	2-4	33 (8.5)	58 (14.9)
	5-9	72 (18.6)	48 (12.4)
	10-14	36 (9.3)	27 (6.9)
	>=15	29 (7.5)	25 (6.4)
History of hypertension	Yes	125 (32.2)	64 (16.5)
	No	58 (14.9)	141 (36.3)

5.6. Primary and secondary prevention of DM and low dose aspirin use

Out of 183 (47.2%) of diabetic patients using low dose aspirin, 37 of them has an indication as per ADA 2020 guideline. Furthermore, 72.9% of patients with indication were taking low dose aspirin while 27.1% of clients were not taking even if they have an indication to use. Among the patients on low dose aspirin 41.9% are taking without meeting the guideline requirement for an indication as primary prevention.

Also, out of the 27 DM patients who have an indication to receive low dose aspirin as secondary prevention, 74.1 %(20 patients) were using low dose aspirin, while 25.9 %(seven patients) of them were not using even if they were supposed to use. (Table 4).

Table 4: Clients adherence to ADA 2020 guidelines to use low dose aspirin

Variables	Categories	Taking low dose aspirin		Chi2	P-value
		Yes	No		
Primary prevention indicated	Yes	39 (10.1%)	14 (3.6%)	17.194	0.000
	No	144 (37.1)	191 (49.2)		
Secondary prevention indicated	Yes	20 (5.2%)	7 (1.8%)	8.432	0.004
	No	163 (42.0%)	198 (51.0%)		
	Total	183 (47.2%)	205 (52.8%)		

5.7. Factors associated with low dose use of aspirin among diabetics

After controlling for confounding effects using multivariable logistic regression, factors influencing the use of aspirin among diabetics were determined as duration of DM, monthly income, age group, dyslipidemia, history of hypertension, and chronic kidney disease/albuminuria.

Duration of DM was significantly influencing low dose aspirin utilization. Diabetic patients who live with DM for 2-4 years duration were more than four times more likely as compared to these living with diabetes mellitus for less than two years [AOR 3.95 (95% C.I. 1.59, 9.82)], those who live 5-9 years with DM more than five times more likely [AOR 5.72 (95% C.I. 3.04, 8.09)], those who live 10-14 years with DM were more than four times more likely [AOR 6.25 (95% C.I. 2.33, 16.75)], and those who live 15 years and above years with DM were about five times more likely [AOR 3.49 (95% C.I. 1.30, 9.35)], as compared to those living with DM for less than 2 years (Table 4).

Age group was found to be a significant predictor of using a low dose of aspirin. Those in the age group of 40-49 years, 50-64 years, and 65 years above were 3.99, 7.28, and 8.51 more likely to utilize a low dose of aspirin as compared to those under 30 years of age (Table 4).

Participants who have a history of hypertension were about twice more likely [AOR 1.97 (95% C.I 1.11, 3.50)] and those who have dyslipidemia were three times more likely [AOR 3.07 (95% C.I 1.60, 5.90)] to utilize a low dose of ASA compared to their counterparts (Table 4).

Table 5: A multi-variable logistic regression model of low dose aspirin use among diabetics on follow up at Jimma Medical Center diabetic clinic, Southwest Ethiopia, in 2020.

Variables	Category	Low dose ASA					
		OR	Std. Err.	Z	P>z	[95% C.I]	
Duration of DM (in years)	<=1	1.00	(base)				
	2-4	3.95	1.84	2.95	0.003	1.59	9.82
	5-9	5.72	3.01	5.38	0.000	3.04	8.09
	10-14	6.25	3.14	3.64	0.000	2.33	16.75
	>=15	3.49	1.76	2.49	0.013	1.30	9.35
Monthly Income (in ETB)	<500	1.00	(base)				
	500-1500	2.41	1.91	1.11	0.267	0.51	11.38
	15001-3000	2.18	1.72	0.99	0.322	0.47	10.21
	3001-5000	3.94	2.94	1.84	0.066	0.92	16.97
	>=50001	2.01	1.47	0.95	0.341	0.48	8.40
Age group (in years)	<30	1.00	(base)				
	30-39	1.15	0.85	0.19	0.849	0.27	4.86
	40-49	3.99	2.29	2.42	0.016	1.30	12.28
	50-64	7.28	6.05	5.28	0.000	4.22	9.72
	>64	8.51	7.65	5.14	0.000	5.86	13.85
History of hypertension	Yes	1.97	0.58	2.30	0.021	1.11	3.50
	No	1.00	(base)				
Dyslipidemia	Yes	3.07	1.02	3.37	0.001	1.60	5.90
	No	1.00	(base)				
Chronic Kidney disease/albuminuria	Yes	1.00	(base)				
	No	1.01	0.43	0.03	0.978	0.44	2.31
Constant		0.03	0.04	-2.40	0.017	0.00	0.53

6. Discussion

This thesis was conducted on 387 diabetic patients to assess the use of low dose aspirin and associated factors for primary and secondary prevention of cardiovascular disease among diabetic patient at Jimma Medical center from September to November 2020.

Of the 387 Diabetic patients, 47.2 % (183) of them use low dose aspirin. This is too much when compared with the findings in the Analysis of the National Health and Nutrition Examination Survey 2011–2012 conducted in the U.S. to examine the use of aspirin for CVD prevention, which showed 40.9% reported being told by their physician to take aspirin, with 79.0% (31.6 % of the total) complying (16).

In this study older age , longer duration of diabetes mellitus, higher educational status ,dyslipidemia ,hypertension, are associated with more likely utilization of low dose aspirin and this is similar with the study done in USA (16).

Among the 27 DM patient with ASCVD, 20(74 %) are on low dose aspirin; which is comparable with the 74.2 % reported in the statewide telephone surveys conducted to assess recent self-reported regular aspirin use among adults 35 years or older with diabetes in 20 states in the USA in 2001.

From this study, 30.6 % of DM patients have inappropriate ASA use for primary prevention which is significant when compared to the study done in USA in the National Cardiovascular Disease Registry's Practice Innovation and Clinical Excellence registry which assessed the frequency and practice-level variation in inappropriate aspirin use for primary prevention in a large U.S. nationwide registry, inappropriate aspirin use frequency was 11.6% in the overall cohort (17)

Among the 387 DM patients, aspirin was indicated for 4.3 % of the patients but it was not prescribed. It was both indicated and prescribed in 12.11 % of the cases. This figure is lower when compared to the study conducted between February 2014 and April 2014 at the General Practice Department of King Abdul-Aziz University Hospital (KAUH) Jeddah, Saudi Arabia, of

312 patients, aspirin was indicated for 17.0% but it was not prescribed. It was both indicated and prescribed in 36.2% of the cases (1).

The limitation of this study is that patients may not properly remember their age and this may change the recommendations for use of ASA as the indication for primary prevention of ASCVD is dependent on age and some of the investigation required in data collection like urine analysis and renal function test are either never done or lost from the chart.

7. Conclusion and recommendation

7.1 conclusion

According to this study, almost half of the DM patients are on low dose aspirin. Among low dose aspirin users for primary prevention, only about one fourth of them meet requirement as per active guideline. While three fourth of the users have no indication to use aspirin, and about half of the patients with an indication to use are not using despite having an indication to use for primary prevention.

In addition, among these patients` with previous major cardiovascular events three fourth are using aspirin, but one-fourth of them are not using even if they were indicated to use low dose aspirin as active guideline Being a diabetic patient for two years and above, age 30 years old and above, having a history of hypertension and having dyslipidemia were found to be more likely factors to use a low dose aspirin.

7.2 Recommendations

To health care workers: recommendations on use of ASA for prevention of major cardiovascular events in DM have been changing and there is a need to update knowledge of the most recent recommendations so as to practice accordingly and avoid irrational use of aspirin.

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Annex I: Information Sheet and Consent Form (English)

A. Information Sheet (English version)

Title of the research project

ASSESSMENT OF LOW DOSE ASA USE FOR PREVENTION OF CVD AMONG DIABETIC OUT-PATIENTS AT JIMMA MEDICAL CENTER

Name of the organization: -

Jimma University, Department of Internal Medicine

Purpose of the study

The Purpose of this study is **a**ssessment of low dose ASA use for prevention of CVD among diabetic out-patients at jimma medical center clinic of Jimma, south west of Ethiopia. So this study will provide such information.

Confidentiality

Any information that will be obtained about you will be kept confidential. This is assured by avoiding use of any identifier about you and information will be recorded with code number. Your information will be used only for this study purpose.

Voluntary participation

Participation on this study is voluntary basis of participant while have the right to refuse on participation at any time. I would like to inform you that ethical clearance was obtained and it will be approved by Jimma University Research Ethical Review Committee. At end, you may ask questions now and in the future if you do not understand something that is being done. Here are addresses of principal investigator and advisors who you can contact:

Name of investigator: - Dr. Nigatu Asfaw Cell number: - 0912686317

Name of advisors: - -Dr. Kedir Negesso (internist) --------

- Habtamu Abebe (MPHE)……..

B. Consent Form (English version)

Participant identification number_____

Full name of participant_____

I have read or information sheet has been read to me fully in my own language the information on it. I understood that the research project has got ethical approval from the Research Ethical Review Committee of the College of Public Health and Medical sciences, Jimma University. And also, I understood well the information about the purpose and benefits of the study, the confidentiality of the information and other information's regarding the study. Therefore, I am volunteer to participate in the study and give information.

I_____ have given my consent freely for the participation on the study on assessment of low dose aspirin use for prevention of CVD and associated factors among diabetic out-patients at Jimma medical center , Jimma, south west of Ethiopia,2020

Participant signature_____, Date_____

Data collector name: _____ Signature: ____Date: _____

Witnesses

1. Name: _____ signature: _____Date: _____

2. Name: _____ Signature: _____ Date: _____

B. የስምምነት ቅጽ (Amharic)

የተሳታፊ መለያ ቁጥር _____

የተሳታፊ ሙሉ ስም _____

በቃለ መጠይቁ የቀረቡ ጥያቄዎችን በሙሉ አንብቤ/በአፍ መፍቻ ቋንቋዬ ሙሉ ለሙሉ ተተርጉሞልኛል። ይህ የምርምር ፕሮጀክት በጂማ ዩኒቨርስቲ የጤናና ህክምና ሳይንስ ኮሌጅ የምርምር አጽዳቂ ኮሚቴ አልፎ እንደመጣ ተረድቻለሁ። እናም በቃለ መጠይቁ የቀረቡ መረጃዎችን በመረዳትና የጥናቱን ዓላማና ጠቀሜታ በመገንዘብ እንዲሁም የግል መረጃዎቼ በመጁሉ ሚስጥራዊነታቸው እንደሚጠበቅ በመተማመኔ በጥናቱ ለመሳተፍና ለቃለ መጠይቁ ፍቃደኛ መሆኔን እገልጻለሁ።

እኔ ---------- በደቡብ ምእራብ ኢትዮጵያ በ2013 ዓ.ም በጂማ ዩኒቨርስቲ የህክምና ማእከል ስኩር ታማሚዎች አስፕሪን መድሀኒት አወሳሰድ ና ተጉዳኝ ምክናቶች ላይ ለሚደረገው ጥናት ለመሳተፍ ያለምንም ተጽዕኖ በገዛ ፍቃዴ መስማማቴን እገልጻለሁ።

የተሳታፊው/ዋ ፊርማ _____, ቀን _____

የመረጃ ሰብሳቢው/ቢዋ ስም: _____ ፊርማ: _____ቀን : _____

እማኝ ምስክሮች

1. ስም: _____ ፊርማ: _____ቀን : _____

2. ስም: _____ ፊርማ: _____ቀን : _____

C. unka walii galtee(Afaan oromo)

Odeeffannoo qoratamaaf kennamu

Ani maqaan koo Dr.Nigaatuu Asfawu yoon ta’u karoora barreeffama eebbaa akkaataa itti fayyadama qoricha Asprinii jedhamuu fi sababoota isaa waliin walqabatan yaalamtoota dhibee shukkaara adeemsifamu irratti hirmaataa akka naaf taataniif kabajaan isin gaafadha. Qorannoon kan adeemsifamu bifa gaaffiif deebiitiin, kaardii yaalumsa keessanii irraa odeeffannoo fudhachuun ta’a. Odeeffannoon qorannoo kanarraa argamu hojii fuuldura adeemsifamuuf bu’aaguddaa kan kennu qoratamaa irrattiimmoo dhiibbaa kan hingeessifnedha. Qorannoo kana keessaas yeroo barbaaddanitti ba’uu kan dandeessan yoo ta’u kun immoo tajaajila isin argattanirratti dhiibbaa hin qaqqabsiisu.

Qorannaa irratti hirmaachuuf yoo walii galtan bakka armaan gadii irratti mallattoon mirkaneessaa.

Galatoomaa

Mallattoo hirmaataa…….

Maqaa qorataa……..

Guyyaa……..

Annex II

Questionnaire on the use of low dose ASA among diabetics on follow up at JMC

01. Chart No._____
02. Age _____
03. Sex: 1. Male 2. Female
04. Area of residence 1. Jimma 2. Other (specify)_____
05. Marital status 1. Married 2. Single 3. Divorced 4. Widowed
06. Educational status _1. Illiterate 2. Up to grade 8 3. 8---12 4. College _____
07. Monthly income _____
08. Duration of DM (years)_____
09. Hypertensive 1. Yes 2. No
10. Current Smoker 1. Yes 2. No
11. Dyslipidemia 1. Yes 2.No
12. Chronic Kidney disease / albuminuria 1. Yes 2. No
13. Have you been taking low dose ASA? 1. Yes 2. No
14. Are you still taking low dose ASA? 1. Yes 2. No
15. If yes to Q 14, for how long (years)_____
16. If yes to Q. 13 and no to Q 14, what was the reason? 1. Not prescribed 2. For dyspepsia 3. For excessive bleeding 4. Other, specify _____
17. If no to both Q 13 and 14, what was the reason? 1. Not prescribed 2. For fear of adverse effects 3. Other, specify _____
18. Did you have heart attack, ischemic stroke or peripheral arterial disease in the past? 1. Yes a. MI b. Ischemic stroke c. PAD 2. No
19. If yes to Q. 18, were you taking ASA at the time? 1. Yes 2. No
20. If yes to Q. 19, for how long (in years) before the CV event? _____
21. Are you taking medications other than ASA? 1. Yes 2. No
22. If yes to Q 22, what is the list of medications? _____