Addis Ababa University

College of Health Sciences

School of Medicine

Department of Internal Medicine

Rheumatic heart disease pattern and treatment experience at Tikur Anbessa Specialized Hospital, Addis Ababa, Ethiopia

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Abstract

Background: Despite high prevalence of RHD in Ethiopia, studies on characteristics, complications, and treatment practices are limited in number. It is therefore important; to describe echocardiographic and clinical characteristics and identify the gaps we have in this setting and our level of care.

Methods: Using a cross-sectional study design 256 patients were recruited over a span of two month between June 01, 2020-july 30, 2020. Using Convenience sampling method, all RHD Patients who visited the cardiac clinic during the study period and who fulfilled the inclusion criteria were included in the study. Data was collected using checklist which included back ground information, clinical characteristics, electrocardiography (ECG) findings, echocardiography finding and both medical and surgical management. Data was first checked manually for completeness and then analyzed using SPSS version 26.0.

Results: Among 256 RHD patients, the median age was 30 years. Females (75%) and patients who had urban area (75.8%) were affected predominantly. The majority had combined valvular lesion(75.5%) and severe/very sever valvular lesion (78.1). MR was the most common valvular lesion (76.4%) followed by MS (73%), AR (59.2%), TR(51.9%), AS(15.5%). Mitral valve was the commonest valve affected (94.8%) followed by aortic valve (60.9%). The valve lesion was complicated by high prevalence of pulmonary hypertension (69.5%), chamber dilatation, symptoms of advanced heart failure (53.6%) and atrial fibrillation (32.4%) and stroke (5.5%). The presence of advanced heart failure was found significantly associated with MS(COR, 2.150; 95% CI, 1.168 to 3.956; P=0.014), AR(COR,1.90; 95% CI,1.112 to 3.250; P=0.019), TR(COR, 3.258; 95% CI, 1.896 to 5.598; P=0.00001), RVSD(COR, 4.456; 95% CI,2.111 to 9.404; P=0.00008), and LA enlargement(COR, 1.069; 95% CI, 1.041 to 1.098; P=0.000). Average annual adherence to secondary antibiotic prophylaxis was 73.58% and only 62.1% of patients had good adherence (taking ≥80% of their prescribed monthly BP prophylaxis dose). Even though 94.8% patients identified to be at high risk for stroke and peripheral embolism were receiving OAC, only 57.6% of patients had therapeutic level INR. Although 83.2% of patients required percutaneous/surgical valve intervention done only for 17.8% of patients with significant urban bias (COR, 7.200; 95% CI, 1.670 to 31.039; P=0.008).

Conclusion: RHD patients were young and middle-aged, predominantly females and had high rate of cardiovascular complication. There is suboptimal use of secondary antibiotics prophylaxis, INR control and limited and biased access to percutaneous/surgical intervention.

Key words: Rheumatic heart disease, Congestive heart failure, Valvuloplasty, Valve surgery

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List of acronyms and abbreviations

ARF -Acute rheumatic fever

AR - Aortic regurgitation

AS - Aortic stenosis

CVD - Cardiovascular diseases

CHF - Congestive heart failure

CHA2DS2-VASc: congestive heart failure, hypertension, age ≥75 years (doubled), diabetes mellitus, prior stroke or TIA or thromboembolism (doubled), vascular disease, age 65 to 74 years, sex category.

DCMP - Dilated cardiomyopathy

ECG - Electrocardiography

ECHO - Echocardiography

GBD - Global burden of diseases

GDP - Gross domestic product

HHD - Hypertensive heart diseases

INR – International normalized ratio

IHD - Ischemic Heart Disease

MR - Mitral regurgitation

MS - Mitral stenosis

NCDs - Non communicable diseases

OAC – Oral anticoagulant

NYHA – New York Heart Association

OHS – Open heart surgery

PR-Pulmonic regurgitation

PS-Pulmonic stenosis

RHD- Rheumatic heart diseases

SSA-----Sub Saharan Africa

TASH – Tikur Anbessa Specialized Hospital

TR- Tricuspid regurgitation

TS- Tricuspid stenosis

VHD---valvular heart diseases

WHO – World Health Organization

WHF –World Health Federation

1. Introduction

Rheumatic fever (RF) and rheumatic heart disease (RHD) are nonsuppurative complications of Group A streptococcal pharyngitis due to a delayed immune response. In both developing and developed countries, pharyngitis and skin infection (impetigo) are the most common infections caused by group A streptococci. Group A streptococci are the most common bacterial cause of pharyngitis, with a peak incidence in children 5–15 years of age(1).

The prevalence of RF and RHD and the mortality rates varied widely between countries and between population groups in the same country, depending upon season, age group, socioeconomic conditions, environmental factors and the quality of health care. In 2015 there were globally estimated 33.4 million cases of rheumatic heart disease, 10.5 million disability-adjusted life-years due to RHD, and 319,400 deaths due to rheumatic heart disease.(5). Although the prevalence has declined in the industrialized countries, RHD remains as a major public health problems and major cause of cardiovascular disease in developing nations and it accounts for approximately 15% of all patient with heart failure in sub Saharan African countries. The economic effects of the disability and premature death caused by these diseases are felt at both the individual and national levels through higher direct and indirect health-care costs(1–5).

Rheumatic valvular disease causes significant morbidity and mortality as a result of hert failure, arrhythmia, thromboembolism, infective endocarditis, and fetomaternal complication.(6–9). Rheumatic heart disease and its complications reduce quality of life, result in loss of income because of poor attendance at work, and, among children, poor scholastic performance.(25).

Much of these morbidity and mortality due to RHD can be prevented by existing therapies(10). Secondary prophylaxis with long-acting penicillin reduces the recurrence of episodes of acute rheumatic fever and RHD progression(11,12). Oral anti-coagulants (OACs) in patients with rheumatic AF can reduce thromboembolic complications, and percutaneous or surgical interventions can improve symptoms and prevent congestive heart failure (CHF)(13–17).

But, reports from developing countries showed that RHD patients usually present late in the disease course at their young age and there is inadequate adherence to secondary prophylaxis and poor control of OAC therapy. In addition, the use of per- cutaneous and surgical interventions in developing countries is limited by the shortage of health facilities and trained staff(18–24, 26).

In Ethiopia despite there is huge burden of the disease, only few studies were done to characterize RHD patients(24,29,30). In a retrospective study of deaths between 1995 and 2001 at the Tikur Anbassa Teaching Hospital, Addis Ababa, Ethiopia, 26.5% of the cardiovascular deaths were due to RHD at a mean age of 25 years and 70% of patients with RHD died from congestive heart failure followed by systemic embolization(11%) and comorbid conditions(11%)(26).

In recent years cardiac centers were established at some public and private health institutions and cardiology training programs have also begun with more cardiac professionals diagnosing and treating patients with RHD. At these centers surgical and percutaneous treatment are being offered but far from the demand. This study aims at assessing the current clinical and echocardiographic characteristics of patients with RHD and the treatment experience in the management of these patients.

The study was considered necessary because it helps to identify the current pattern of RHD and management experience in our setting which will help us to design strategies amenable to our setting to improve its prevention, detection, and possibly treatment before complication emerges.

This study will be the bases to conduct further research at community level. The study is also aimed to sensitize policy makers and planners for further detailed disease burden assessment and to design appropriate policy response for existing challenge both for primary prevention and timely interventional management. Therefore, this study was carried out to describe pattern and treatment experience of RHD at TASH cardiac follow-up clinic.

2. Literature review

2.1. Burden of RHD

Rheumatic heart disease (RHD) is a consequence of the damage to heart valves as an immunologic sequel to antecedent group A streptococcal infections. Rheumatic heart disease predominantly affects children and young adults at the peak of their productivity because of their predilection to streptococcal infections. Although RHD has largely disappeared from developed countries, it continues to be a major cause of premature death and morbidity in low- and middle-income countries(1,4,27,28).

Systematic review on global burden of RHD on 132 countries over a period of 25 years, from 1990-2015 showed Global age-standardized mortality due to rheumatic heart disease decreased by 47.8% from 1990 to 2015, but large differences were observed across regions, the highest age-standardized mortality and prevalence of rheumatic heart disease were observed in Oceania, South Asia, and central sub-Saharan Africa. In 2015 there were 33.4 million cases of rheumatic heart disease, 10.5 million disability-adjusted life-years, 319,400 deaths due to rheumatic heart disease globally(5,28).

Another review of 4549 patients in 8 sub-Saharan Africa countries from 12 clinical studies,1957-2005, revealed hypertension(23%), cardiomyopathy(20%) and rheumatic heart disease(22%) account for more than two-thirds of cardiac disease cases and present mostly in the young, economically active population. Ischemic heart disease is rare (13%) in SSA. The remaining 22% of heart failure cases are attributed to corpulmonale and pericarditis, reflecting the considerable impact of infections, including tuberculosis and human immunodeficiency virus (HIV) on heart disease in Africa(4).

The largest multicenter registry for heart failure from July 1, 2007 to June 30, 2010 in 1006 Africans from nine SSA countries including Ethiopia, the sub- Saharan Africa Survey of Heart Failure (THESUS-HF) showed a shift in the CVD profile with an increasing major contribution of hypertension as a cause of heart failure (from 23% to 43%), an increasing importance of cardiomyopathies (from 20% to 29%), a reduced recognition of rheumatic heart disease (from

22% to 17%), and a rise in ischemic heart disease (from 2% to 8%) in the etiology of heart failure as compared to data prior to 2005(3,4).

During a five year period, from 2003 to 2008, a cross-sectional study was conducted on 781 cardiac patients who are newly enrolled to the cardiac follow up clinic of Jimma university specialized hospital found that RHD was most common diagnosis(32.8%) followed by HHD(24.2%) and cardiomyopathic heart diseases(20.2%)(29).

In a cross-sectional study done in Ethiopia from six main referral/teaching hospitals, from 1 January 2015 to 30 June 2015, among total of 6275 patients (58.5% females) valvular heart disease was the most common diagnosis (n=2541, 40.5%) and most of VHD patients were chronic rheumatic heart disease(n= 2184, 86%)(30).

In a multisite echocardiography-based screening in Ethiopia among 3238 school children (48.5% females) 44 (1.4%) met the WHF criteria for definite RHD, while 15 (0.5%) met the criteria for borderline disease, yielding a prevalence of 19 [13.9–23.4, 95% CI] cases per 1000 school children between the ages of 6–18 years. Definite RHD involved the mitral valve in 42 subjects, 39 of whom had mitral regurgitation and 3 with mitral stenosis. The aortic valve was affected in 6 children(24).

2.2. Clinical and echocardiographic pattern of RHD

In a 5 year (July 2008-June 2013) retrospective analysis of newly diagnosed 1001 RHD patients (females= 53%) in sub-Himalayan region, mitral regurgitation (61.9%) was the most common valvular lesion. Heart failure (35.1%), severe pulmonary arterial hypertension (11.7%), and atrial fibrillation (21.1%), infective endocarditis (7.4%) and death due to RHD (3.2%) were common complications(31).

From retrospective review of 10860 transthoracic echocardiography reports between June 1999 and February 2011 in eastern Nepal RHD was diagnosed in 1713(15.77%) patients, 1055 female and 658 male, and 25.7% of the patients were below 20 years of age. Mitral regurgitation was the most common valvular lesion across all age groups irrespective of sex (77.1%). Female patients were significantly older and more commonly presented with mitral stenosis as compared to male patients at the time of presentation. Conversely, aortic regurgitation was more common in men as

compared to women. Both the mitral and aortic valve was involved in 49.8% of the patients and was more common in men as compared to women(32).

A hospital based descriptive cross-sectional study in a tertiary care hospital in Central Nepal at College of Medical Sciences-Bharatpur, from June 2014 to April 2016, included 235 RHD patients(F:M=2.1:1) age ranged from 7 to 76(mean age 39.82 ± 4.2 years). The predominantly involved isolated valve was mitral (46.80%) followed by isolated aortic valve (9.36%) and 33.62% had dual valvular involvement. The common rheumatic valvular lesions were pure mitral stenosis (13.61%), isolated mitral regurgitation (24.68%), combined mitral stenosis/regurgitation (15.32%), combined mitral/aortic regurgitation (9.78%) and combined aortic stenosis/regurgitation (7.66%). The common complications encountered were heart failure (38.30%) and arrhythmias (51.00%). 55.32% of patients received injectable benzathine penicillin whereas 419.15% of patients preferred oral penicillin V. Surgical intervention was done in 54 (22.97%) patients and 12 (5.10%) expired in the CCU during the course of treatment(33).

In another retrospective analysis in a Tertiary Care Hospital of Western Nepal from January 2009 to December 2015, among 12567 trans-thoracic echocardiography 609 (4.84%) patients were RHD including post valve replacement patients. Most patients were females and belonged to age group of 21-40 years. The commonest isolated lesion was mitral regurgitation (26.21%) followed by mitral stenosis (6.82%). The commonest mixed lesion was MS with MR and aortic regurgitation (AR) seen in 99(21.8%). The frequency of atrial fibrillation (AF) and stroke was found in 18% and 3% of RHD patients respectively(34).

From another prospective clinical registry in Soweto, South Africa, during 2006/07, among 4005 new presentations 960 (24%) had a valvular abnormality. Of these, 344 cases (36%) were diagnosed with RHD. Most were black African females (68%). The predominant valvular lesion was mitral regurgitation (59%), with 14% and 13% cases, respectively, having combination lesions of aortic plus MR and mixed mitral VHD. Impaired systolic function was found in 14% of predominant MR and in 18% with predominant aortic regurgitation. Elevated right ventricular systolic pressure, atrial fibrillation, and anemia were found in 18, 10, and 8% of RHD cases, respectively. About 26% of patients were admitted within 30 months of initial diagnosis for suspected bacterial endocarditis. Subsequent valve replacement/repair was performed in 22% of patients(35).

In a retrospective study in Makurdi Nigeria among 231 echocardiography done from May 2013 to April 2017 about 36(15.6%) of these had an echocardiographic diagnosis of rheumatic heart disease with female predominance (ratio 1:2.6) and an age range of 5 to 81 years and a mean age of 46.61 ± 19.6 years. The commonest rheumatic lesion was isolated mitral regurgitation (27.8%) followed by combined mitral and aortic valve disease (19.4%) and then mixed aortic valve (13.9%). Others less common lesions were aortic regurgitation in(11.1%), aortic stenosis (11.1%), mixed mitral valve disease (8.3%) and isolated mitral stenosis(8.3%). Common complications identified were valvular cardiomyopathy (33.3%), secondary pulmonary hypertension (27.1%), atrial fibrillation (20.8%), functional tricuspid regurgitation (16.7%) and infective endocarditis (2.1%)(36).

In a retrospective analysis of 376(females=57.4%) children with rheumatic heart disease at Uganda Heart Institute, Mulago hospital, from January 2007-December 2011, the mean age of the children was 11.0±2.7 years. The identified valvular lesions were mitral regurgitation in 98.9% (severe in 73.1%), aortic regurgitation in 51.3% (severe in 7.2%), mitral stenosis in 10.6% (severe in 5.9%), and tricuspid regurgitation in 86.7% (severe in 8.2%) while aortic stenosis was seen in 1.3% (severe in 0.3%) of children. Children with MS were older than those without MS(37).

Another cross-sectional study done in Uganda (June 2010-January 2012) at Mulago Hospital, a total of 309 (115 males and 196 females) definite rheumatic heart disease patients aged 15–60 years were enrolled in the study and complications occurred in 49% (152/309) of patients. These complications were heart failure (46.9%) pulmonary arterial hypertension (32.7%), atrial fibrillation (13.9%), recurrence of acute rheumatic fever (11.4%), infective endocarditis (4.5%) and stroke (1.3%). Atrial fibrillation and acute rheumatic fever were the most common complications associated with heart failure(38).

In a retrospective study on 805 (female=52.4%) rheumatic heart disease patients in Southern Yemen, Aden city, from January 1999 to December 2003 age range was 4-70 years; mean age, 28.6 ± 14.5. The valve lesion distribution was mitral 459 (57.1%), aorta 70 (8.7%) and both valves 276 (34.2%). About 55.2% of patients had isolated lesion and remaining had multiple

lesions. The most common valvular lesion was mitral regurgitation (57.6%) followed by mitral stenosis (50.3%), aortic regurgitation (40.6%) and aortic stenosis (6.7%). All children aged less than 10 years had regurgitation while adolescents and young adults commonly had Stenosis and multiple valve lesions. Pulmonary hypertension was the most common complication (80.4%). Although moderate and severe lesions detected in 51% cases only 34.8% of patients at severe stage were operated(39).

Prospective descriptive study on 114 (female=66%) patients between January 1994 and January 1995 at Gondar College of Medical Sciences Teaching Hospital showed the mean and median age of the patients were 23 +/- 8 years and 22 years, respectively, (range = 5-50 years). Only 26% of the patients gave history suggestive of RF and 5.3% had siblings with similar illness. The most common valve lesion found was combined mitral regurgitation and stenosis seen (25.4%), followed by pure mitral stenosis (21.9%) and mitral regurgitation (18.4%). The common complications identified were heart failure (58%), atrial fibrillation (22.8%), and recurrence of rheumatic fever (9.6% over the study period)(40).

In a retrospective study of deaths between 1995 and 2001 at the Tikur Anbassa Teaching Hospital, Addis Ababa, Ethiopia, Combined mitral and aortic valve disease accounted for majority (42.6%) of the lesions followed by combined mitral regurgitation and stenosis (24.4%). Isolated mitral stenosis, or regurgitation was a relatively less and aortic valve lesion without mitral valve involvement was rare (3.5%). The common cause of death in RHD patients was congestive heart failure(70%) followed by systemic embolization (11%0 and comorbid conditions(11%)(26).

In the VALVAFRIC study which is a multicenter hospital-based retrospective registry of patients with RHD hospitalized in Western and Central African cardiology departments from 2004 to 2008, Among 27,822 hospitalized patients, 3441 patients had RHD (females=60%) and 1385 had severe lesions which was higher in countries with the low income and lack of schooling. The most common valve lesion was mitral regurgitation (52.8%) followed by aortic regurgitation (32.1%), mitral stenosis (13.4%) and aortic stenosis (1.8%). Combined valvular lesions were observed in 13% of cases. Common complications found were heart failure 40%), major left ventricular dilatation (13.6%0), left atrial dilatation (13.8%), dilatation of the right cardiac chambers (19.8%) and pulmonary hypertension (28.7%). In-hospital outcomes included death

(16%), heart failure (62%), arrhythmias (22%), endocarditis (4%) and thromboembolic events (4%). Subsequently, 176 patients were readmitted (13.6%)(18).

The Global Rheumatic Heart Disease Registry(REMEDY study) done at 25 hospitals in 12 African countries (including Ethiopia), India, and Yemen between January 2010 and November 2012 prospective enrolling 3343 RHD patients (median age 28 years, 66.2% female) showed the majority of cases of mitral stenosis(72.9%), mitral regurgitation (60.4%), pulmonary stenosis (59.4%), tricuspid stenosis (54.2%), and aortic stenosis (61.9%) had moderate-to-severe disease, whereas the majority of cases of aortic regurgitation (55.2%) were mild. The majority (63.9%) had moderate-to-severe multi-valvular disease complicated by congestive heart failure (33.4%), pulmonary hypertension (28.8%), atrial fibrillation (AF) (21.8%), stroke (7.1%), infective endocarditis (4%), and major bleeding (2.7%). One-quarter of adults and 5.3% of children had decreased left ventricular (LV) systolic function; 23% of adults and 14.1% of children had dilated LVs(20).

2.3. Experiences and gaps in managing RHD

The VALVAFRIC study which was done in Western and Central African countries showed that access to surgical care was extremely low. Only 27 of 1200 patients (2.2%) requiring surgical intervention were operated, all done after transferred abroad for cardiac surgical care(18).

In a prospective registry of 2,005 patients of RHD over a period of 6 years (2011 to 2016) in India, although, overall Evidence-based use of oral anticoagulant therapy was high (77.7% of high-risk patients) the use of secondary prophylaxis was low (28.5%)(41).

The Global Rheumatic Heart Disease Registry (REMEDY study) done at 25 hospitals in 12 African countries (including Ethiopia), revealed gaps in the implementation of medical and surgical interventions of proven effectiveness for RHD in low- and middle-income countries. Nearly half (45.2%) of participants in this study were not on antibiotic prophylaxis at the time of enrolment. Although OACs were prescribed in 70% of patients with these indications, International normalized ratio control was however poor, with only 1 in 4 patients on OACs having therapeutic INR levels at the time of enrolment. This study also showed lack of reproductive services for women with RHD, and disparities in the use of percutaneous and surgical interventions between different countries, extremely low (13.6%,152/1110) in low-

income countries compared with upper-middle-income countries, despite the greater prevalence of patients with RHD and LV dysfunction who require these interventions in low-income countries(20).

A retrospective study in Brazil on 536 patients with diagnosis RF from 1985 to 2005 showed high rate of non-adherence to secondary prophylaxis (35%) and follow up which lead to recurrent episodes of rheumatic fever(23).

In a cross-sectional study conducted on 241 RHD patients at cardiac clinic of Jimma Medical Center (JMC), Ethiopia, from June 1-September 30, 2018, , revealed low adherence rate (55.2%) to the secondary prophylaxis due to lack of money, far distance from the setup, painful injection especially among children and lack of awareness about the disease(21).

Recently published (in 2020) another cross-sectional study done at the Adult Cardiac Clinic of Tikur Anbessa Specialized Hospital (TASH) included145 participants and the average adherence rate to monthly BPG injection was high (80.60%). However, only 101 (69.7%) of participants were taking ≥80% of their prescribed monthly BPG prophylaxis doses(42).

In a retrospective review of clinical Outcomes of Children Operated for Rheumatic Valvular Heart Disease in a Tertiary Hospital in South Africa; from January 2008 to December 2015, total of 24 patients were operated for RHD and had good outcomes even if they operated with severely dilated left ventricle due to severe mitral valve regurgitation. Also the post-surgery follow up demonstrate improvement of ventricular function in those patients that had poor left ventricular function pre-operatively(16).

In a retrospective study on 2,612 patients who were subjected to an OHS in Cote d'Ivoire between 1978 and 2013 1,475 were cases of rheumatic heart diseases (RHD), and a total of 1,481 valvular replacements (bioprostheses n=489, mechanical prostheses n=992) and 445 valvular repair were carried out successfully with low hospital and late mortality(being 6.7% and 8.7% respectively(17).

A retrospective review of 54 patients who underwent surgery for RHD from March 2007 to May 2015, in Rwanda, and subsequent follow-up at rural district hospitals showed the possibility of good outcomes in rural and resource-limited settings of patients with RHD after heart surgery by using a decentralized care model. Majority of patients were adults (85%), females (74%) and presented with advanced heart failure symptoms (83% before surgery and only 4% afterwards). The mitral valve was the most common valve requiring surgery and most of valvular surgery was single valve (56%) and double valve (41%). After surgery with in a median of 3 years (range 0.2–7.9) follow-up 7.4% of them died; all deaths were patients who had undergone bio-prosthetic valve replacement. For patients with mechanical valves, anticoagulation was checked at 96% of visits. There were no known bleeding or thrombotic events requiring hospitalization(15).

A combined retrospective and prospective cohort study done in Khartoum (January 2005– March 2018) included a total of 818 children (51% males) and follow outcomes of operated and un-operated children. The study reviled high mortality for un-operated patients and operative mortality improved although the follow-up rates are poor and adverse outcomes are common(13).

In a review of cardiac surgery for VHD cases at TASH in Ethiopia over a 30 year period (1983 to 2013) a total of 157 valve surgeries were done. Mean age at time of surgery was 26.7 years and females constituted 66% of the cases. Over 90% were from cities or big towns of the country showing dramatic urban bias in access to cardiac surgery. Patients with rheumatic heart disease were younger, more likely to be female and have atrial fibrillation. More than 75% of the surgical procedures done were mechanical valve replacement. Mechanical valves, compared with bio-prosthetic valves, were more likely to be used in patients with rheumatic heart disease and younger patients(43).

A cross-sectional study was conducted using data collected from 20 patients who under- went valve surgery from May 2017 up to March 2018 at the Cardiac Center of Ethiopia by a local team. Patient's age ranged from 9 to 75 years with mean age of 26.4 years. Among 20 patients15 (75%) patients received mechanical valve replacement, while 2/20 (10%) had tissue valve replacement. Three patients underwent mitral valve repair and three patients had double valve replacement. Two patients underwent mitral valve replacement plus left maze procedure. There was one death for whom mitral valve replacement done(44).

3. Objectives of the Study

3.1. General Objective

- To describe characteristics and experiences in managing RHD patients at TASH

3.2. Specific Objectives

- To describe the demographic characteristics of the affected patients
- To describe echocardiographic pattern of RHD at cardiac clinic of TASH
- To assess the clinical characteristics and common complications of RHD
- To assess treatments experience particularly secondary antibiotic prophylaxis, oral anticoagulation therapy and surgical and percutaneous interventions.

4. Methodology

4.1 Study Area

This study was conducted in Addis Ababa University College of health science TASH, Internal Medicine Department, cardiac unit. Tikur Anbessa Specialized hospital is one of the largest tertiary referral public hospitals in the country. It was opened in 1972 and become the only site for training medical doctors in the country. In 1998, with 700 beds, it was transferred to school and become a university teaching hospital. TASH is now the main tertiary teaching hospital and providing specialized clinical services, to the whole nation, which is not available in other public or private hospitals.

Currently TASH is a huge residency and sub specialization center in many fields. The outpatient service includes a number of clinics from each clinical department. Under the department of Internal Medicine, there are a number of subspecialty units and clinics including the cardiac unit. The cardiac unit has its own ward, CCU, ECHO room and outpatient clinic. TASH is the only public hospital that contains cardiac center that provide cardiac surgical service in the country.

4.2. Study Period

- The study was conducted between June 1, 2020 to July 30, 2020.

4.3. Study Design

- Institutional based descriptive Cross sectional study design

4.4. Source Population

- Patients with cardiac diseases on follow up at the cardiac clinic.

4.5. Study Population

- Patients diagnosed with RHD visited the clinic during the study period and who gave consent to the study

4.6. Eligibility criteria

4.6.1. Inclusion Criteria

- Patients who had echocardiography
- Documented diagnosis of RHD(2012 World Heart Federation criteria for the echocardiographic diagnosis of rheumatic heart disease will be applied to reach the diagnosis)(45)

- ❖ Patients who were willing and provided informed consent
- ❖ Patients who had clinical evaluation and follow up at cardiac clinic of TASH

4.6.2. Exclusion Criteria

- ❖ Patients who were not willing or not able to give consent
- ❖ Patients who do not have echocardiography and complete chart documentation
- ❖ Patients with primary diagnosis of valvular disease other than RHD (eg, degenerative disease).

4.7. Sample Size

A sample size of 350 patients was calculated using the formula for a single population proportion taking 95 % confidence interval, 5% margin of error and proportion (p) of 0.35. This proportion was taken from a cross-sectional study done in Ethiopia from six main referral/teaching hospitals, from January 2015 to 30 June 2015, among total of 6275 cardiac patients. The estimated source population was <10,000 and so the sample size was recalculated using reduction formula, based on the estimated source population during the study period and results in final sample size of 256.

4.8. Sampling Method

Using Convenience sampling method, all consecutive RHD patients who visited the cardiac clinic during the study period and who fulfilled the inclusion criteria were included in the study.

4.9. Data Collection Instruments & Techniques

Data was collected by trained paramedics, internal medicine residents who are working at cardiac clinic during study period and by the principal investigator using checklist which included back ground information, clinical characteristics, electrocardiography (ECG) findings, echocardiography finding and both medical and surgical management. Patient's chart or electronic medical record was used to retrieve clinical, ECG and echocardiographic findings. Treatment profile emphasizing penicillin prophylaxis, oral anticoagulants and percutaneous or surgical intervention was collected from patient interview and record review. The adequacy of OAC therapy and adherence to penicillin prophylaxis was assessed by retrieving the most three recent international normalized ratio (INR) values and by direct questioning respectively.

4.10. Variables

4.10.1 Independent Variables

- ❖ Socio-demographic factors-age, sex, level of education, residence, employment status.

4.10.2 Dependent variables

- ❖ Pattern and severity rheumatic valvular heart diseases (MR,MS, AR, AR,TS, TR,)
- ❖ Cardiovascular complications (arrhythmia, thromboembolic event, PHTN, heart failure/LV dysfunction)
- ❖ Pharmacologic management and percutaneous or surgical intervention for valve disease

4.11. Operational Definitions

- ❖ RHD: diagnosed by cardiologist doing the echocardiography based on 2012 WHF criteria
- ❖ Stroke: defined by a physician based on sudden onset of neurologic deficit consistent with ischemia/infarction of a vascular territory, lasting 24 h, with or without confirmation by neuroimaging
- ❖ Atrial fibrillation or flutter: Physician diagnosis with or without ECG evidence of atrial fibrillation or flutter.
- ❖ Advanced heart failure: a patient having NYHA class III or IV heart failure symptoms and any of the following three criteria:

    i. Signs (rales, increased jugular venous pressure or ankle edema) or symptoms (dyspnea on exertion or at rest, orthopnea, nocturnal paroxysmal dyspnea, or ankle edema) of congestive heart failure,

    ii. Radiologic signs of pulmonary congestion, and

    iii. Treatment with diuretics

- ❖ Indicated for Oral anti-coagulants:(14)
    - o Presence of AF in patients with mechanical valve/mitral repair or rheumatic mitral stenosis (MS) irrespective of the CHA2DS2-VASc score.
    - o Patients with AF and a CHA2DS2-VASc score of 2 or greater with native aortic valve disease, tricuspid valve disease, or MR

- INR target range for mechanical prosthetic valves is 2.5–3.5, while target range for rheumatic atrial fibrillation or mitral stenosis in sinus rhythm with high-risk features is 2.0–3.0.
- Major bleeding: Patient has bleeding with any of the following three criteria
  i. Fatal
  ii. Involves a critical site (intracranial, retroperitoneal, intraspinal, intra ocular, pericardial, or intra-articular)
  iii. Leads to a reduction in hemoglobin level ≥2 g/dL, or requires transfusion of ≥2 units of whole blood or packed red cells
- Good adherence or adhered to secondary antibiotics prophylaxis: if the rate of adherence is covering >= 80% of prophylaxis. i.e. patient was not missed any injection or only missed less than three times injection in the last 1 year or received prophylaxis at least ten times).
- Poor adherence or not adhered to prophylaxis: if the rate adherence is <80%, i.e. patient had missed their regular injection more ≥3 times in the last 1 year including patients who were not taking secondary antibiotic prophylaxis
- Percutaneous valvular interventions: Percutaneous balloon dilatation of stenosed mitral, aortic, tricuspid, or pulmonary valves
- Valve surgery: Performance of any valve repair, or replacement of valve with a tissue, or mechanical prosthesis
- Indication for percutaneous or surgical intervention: recommended by treating physician based on 2017 AHA/ACC Focused Update of the 2014 AHA/ACC Guideline for the Management of Patients With Valvular Heart Disease(14).

4.12. Data Processing and analysis

The data was entered to SPSS version 26.0 software. The data was cleaned and rechecked for its consistency. The descriptive statistics of the study population were reported as counts and percentages for categorical variables and mean for continuous variables with normal distribution. The strength of association between independent variables with outcome variables was reported as odds ratios (ORs) with 95% confidence intervals (CIs). Data analysis was done using SPSS version 26.0 software and the result presented by tables, pie charts and graphs. P-values of less than 0.05 were considered statistically significant.

4.13. Data quality Management

To ensure the quality of data, preceding data collection, the data collectors were trained by the principal investigator on the objective, relevance of the study and confidentiality of information. The questionnaire was prepared in English then it will be translated to Amharic during interview. The questionnaire was pre-tested to learn about appropriateness of the questions.

4.14. Ethical Consideration

Before conducting the study, the study proposal was submitted to department of internal medicine and ethical clearance was obtained from department of internal medicine and Institutional Review Board (IRB) of College of Health Sciences. Patients were informed about the aim, benefit and possible inconvenience of the study. They were assured the information they gave will be confidential. Before data collection begins, Verbal consent was obtained and participant's withdrawal was assured at any time if the need arises.

4.15. Dissemination of results.

The findings of the study will be submitted to the department of internal medicine and all efforts will be made to publish the results to the local and international journals and to present it in national scientific conferences.

5. Results

5.1 Socio demographic characteristics

A total of 256 patients with a documented diagnosis of CRVHD during follow up were included in the study, out of which 64(25%) were males and 192(75%) were females giving a female to male ratio of 3:1. The minimum and maximum age of the patients was 13 and 70 years respectively, with mean and median age of 32.01 and 30 respectively. The median ages were 26 and 32 for males and females respectively. The majority 156(60.9%) of the patients were age 20-49years (Table-1). About 75.8% (194) of patients were from urban and 24.2% (62) patients from rural (**Table 1**). About 60(23.4%) of patients had no formal schooling, while 23% had completed primary school; the remainder had completed secondary school (24.2%) or graduated from college/university (29.3%). The majority 129(50.4%) of patients were unemployed; the remainder are self-employed (34.8%) and government employed (14.8%).

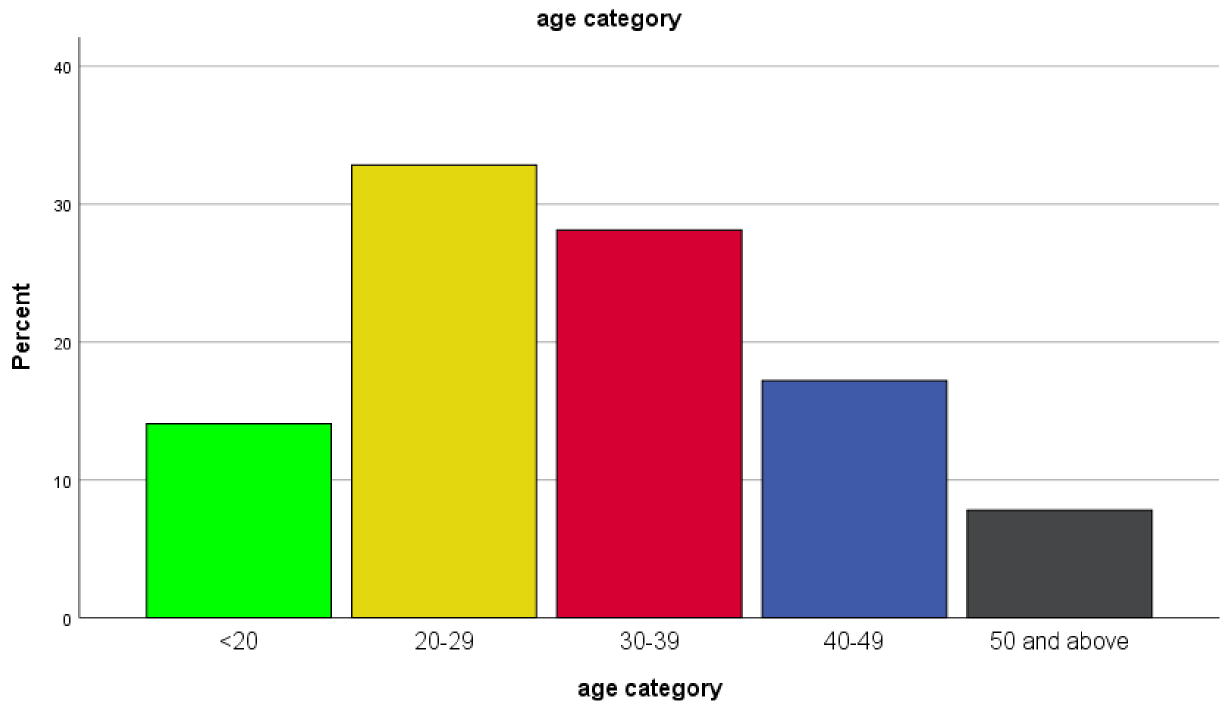

Figure 1: Distribution of age group in patients with RHD following at cardiac clinic in TASH, 2020 (n=256)

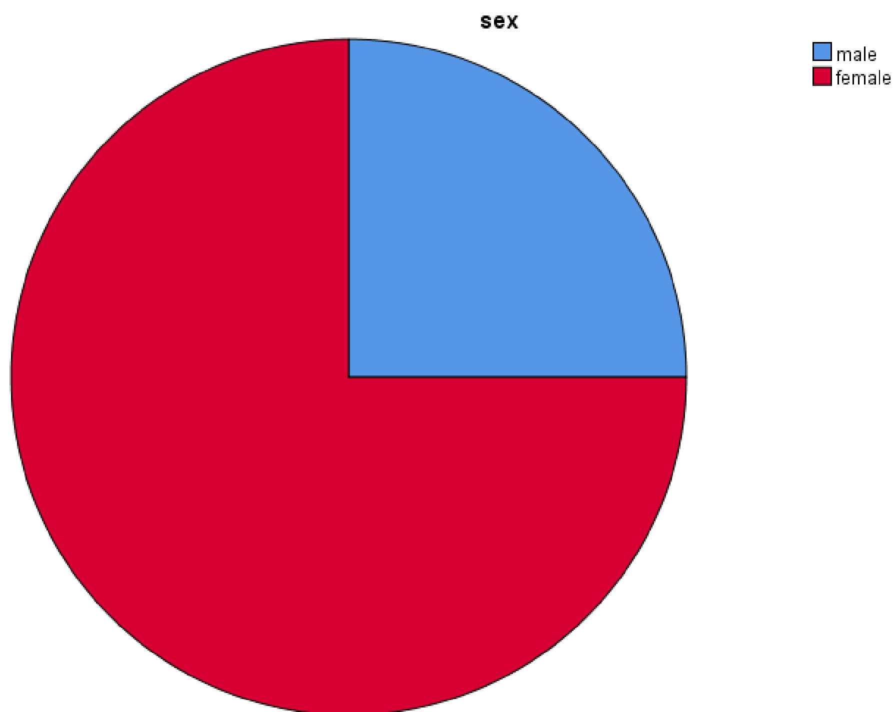

Figure 2: Distribution of sex in patients with RHD following at cardiac clinic in TASH, 2020 (n=256)

Table 1: socio-demographic charactestics of CRVHD patients TASH ,Addis Ababa, 2020 (n=256)

Charctestics	number	percentage
Gender		
Male	**64**	**25**
Female	**192**	**75**
Age category (in years)		
<20	36	14.1
20----29	84	32.8
30----39	72	28.1
40---49	44	17.2
50 and above	20	7.8
Residence		
Urban	194	75.8
Rural	62	24.2
Educational Level		
Illiterate	38	14.8
Read and write	22	8.6
primary education	59	23
secondary education	62	24.2
Higher education	75	29.3

Occupation		
Government Employed	38	14.8
Self employed	89	34.8
Unemployed	129	50.4

5.2 Echocardiographic pattern and severity of valvular dysfunction

Patients without valvular intervention and among patient for whom valvular intervention was done and has preprocedure ECHO were included in the analysis of echocardiographic data including pattern and severity of valvular involvement and complications (**Table 2, Table 3).**

Among these 233 patients the most common valvular lesion was MR(178, 76.4%) followed by MS(170, 73%), AR(138, 59.2%), TR(121, 51.9%), AS(36, 15.5%), TS(11,4.7%), PR(4, 1.7%) and PS(1,0.4%). Considering the highest valvular lesion majority (182, 78.1%) of patients had severe valvular lesion and while assessing the severity of individual valvular lesions, 43 patients (24.2%) had severe MR, 144 patients (84.7%) had severe or very severe MS, 23 patients (16.7%) had severe AR, 12 patients (33.3%) had severe AR and 58 patients (47.9) had severe TR (Table 2).

The distribution of valvular lesion was isolated mitral regurgitation (MR) in 12 (5.2%), isolated MS in 10(4.3%), isolated AR in 7(3%), isolated AS in 2(0.9%).isolated MVD in 44(18.9%) and isolated AVD in 12(5.2%). Mitral valve was involved in 221(94.8%) while aortic valve involvement identified in 142(60.9%) patients. MMVD(combined MS and MR) in 127(54.5%), MAVD(combined AS and AR) in 32(13.7%). Majority of the patients(75.5%) had combined valvular lesion with MMAVD in 130(55.8%), MMTVD in 124(53.2%), MMATVD in 78(33.5%) and all the four valves involved in 1 patient (Table 3).

Table 2: Distribution and severity of valvular dysfunction CRVHD patients TASH ,Addis Ababa, 2020 (n=233)

Valvular leson	number	percentage (%)
MR	178	76.4
Mild	72	40.4
Moderate	63	35.4
Sever	43	24.2
MS	170	73
Mild	11	6.5
Moderate	15	8.8
Sever	80	47.1
Very sever	64	37.6
AR	138	59.2
Mild	63	45.7
Moderate	52	37.7
Sever	23	16.7
AS	36	15.5
Mild	8	22.2
Moderate	16	44.4
Sever	12	33.3
TR	121	51.9
Mild	40	33.1
Moderate	23	19.0
Sever	58	47.9
TS	11	4.7
Mild	4	36.4
Moderate	4	36.4
Sever	3	27.3
PR	4	1.7
Mild	2	50
Moderate	1	25
Sever	1	25
PS	1	0.4
Mild	0	0
Moderate	1	100
Sever	0	0

Table 3: Echocardiographic Patterns of valvular involvement in CRHD patients TASH ,Addis Ababa, 2020(n=233)

Charctestics	number	percentage
Monovalvular lesions		
Isolated MR	**13**	**5.6**
Isolated MS	**10**	**4.3**
Isolated AR	**7**	**3**
Isolated AS	**2**	**0.9**
MVD	**221**	**94.8**
Isolated MVD	**44**	**18.9**
AVD	**142**	**60.9**
Isolated AVD	**12**	**5.2**
Combined lesions		
MMVD	127	54.5
MAVD	32	13.7
MMAVD	130	55.8
MVD_AR	128	54.9
MVD_AS	31	13.3
MMTVD	124	53.2
MMPVD	5	2.1
MMATVD	78	33.5
MMATPVD	1	0.4
Valve lesion severity		
Mild	**12**	5.2
Moderate	39	16.7
Severe/very severe	**182**	78.1
Other echocardiographic findings		
Mean LA diameter	47.5	
LA diameter>55mm	51	21.9
LA /LAA thrombus	7	3
Mean LVEDD	47.11	
LVEDD >55mm	40	17.2
Mean LVESD	32.91	
LVESD >45mm	21	9
RV dilatation	36	15.5
RVSD	42	18
EF(n=232)		

Mean	59.16	
Preserved EF(≥50)	221	95.3
Midrange EF(40-49)	7	3
Reduced EF(<40)	4	1.7
PHTN	162	69.5
Mild	35	21.6
Moderate	35	21.6
Severe	92	56.8

5.3 Clinical characteristics and complications

Out of total 233 patients pulmonary hypertension was identified in 160 (69.5%) patients (mild-21.6%, modrate-21.6 and severe 56.8%). Marked left atrial dilatation (>55mm) was seen in 51 patients (21.9%). The average value of LVEDD, LVESD, and EF was 47.11mm, 32.91mm and 59.16% respectively. Left ventricular dilatation (LVEDD>55mm) and right ventricular dilatation was seen in 40(17.2%) and 36(15.4%) patients respectively. Echocardiographic assessment of ventricular function revealed left ventricular systolic dysfunction (EF<40%) in 4(1.7%) patients and RV systolic dysfunction in 42(18%) patients (Table 3).

Out of total 256 patients 128(50%) patients diagnosed with in the last 5 years and 57(22.2%) patients diagnosed before 10 years. Majority of patients (237, 92.5%) were symptomatic at some point since the diagnosis while symptoms of advanced heart failure (NYHA functional classes III and IV) was reported in 137(53.6%) of patients. Overall 62(24.2) patients had been hospitalized in the last one year period out of which 8(3.1%) patients and 4(1.6%) patients hospitalized twice and three times respectively. Arrhythmia was diagnosed in 86(33.6%) patients out of which atrial fibrillation was the most common arrhythmia identified in 83(96.5%) patients followed by AVB(2 patients) and atrial flutter(1 patients). Thromboembolic complications like stroke and peripheral thromboembolism were reported in 14(5.5%) and 1(0.4%) of patients, respectively. Left atrial and/or left atrial appendage thrombus was seen in 7(3%, N=233) patients (**Table 3 and Table 4**).

Table 4: clinical characteristics and complications of CRVHD patients TASH ,Addis Ababa, 2020 (n=256)

Charctestics	number	percentage
Duration Since the diagnosis		
0-5years	128	50
6-10 years	71	27.7
11-20 years	49	19.1
>20	8	3.1
NYHA Class		
I	19	7.4
II	100	39.1
III	79	30.9
IV	58	22.7
One year hospitalization		
0 (not hospitalized)	194	75.8
1(hospitalized once)	50	19.5
2(hospitalized twice)	8	3.1
3(hospitalized three times)	4	1.6
Arrhythmia	86	33.6
AF	83	96.5
A. flutter	1	1.2
AVB	2	2.3
Thromboembolic events		
Stroke	14	5.5
Peripheral thromboembolism	1	0.4

5.4 Treatment Practices

5.4.1 Medical management

Overall 34(13.3%) patients were not taking secondary antibiotic prophylaxis while 222(86.7%) patients were taking it (1 patient oral erythromycin others intramuscular penicillin) with different adherence rate. Including patients who are not taking secondary antibiotic prophylaxis average annual adherence was 73.58% while 132(51.6%) patients had 100% adherence, 27(10.5%) patients missed their annual doses <3 times and 63(24.6%) patients missed ≥3 of their annual doses(**Table 5).**

Among 96 patients identified to be at high risk for stroke and peripheral embolism (atrial fibrillation/flutter, mechanical valve, LA/LAA thrombus and previous embolism) 91(94.8%) patients were on OAC (90 warfarin and 1 NOAC). Among 90 patients who were taking warfarin, on the last three hospital visit, only 56(62.2%) patients have INR determination three times while

22(24.4%) patients had INR determination twice, 7(7.8) patients had INR determination once and 5(5.6%) has no INR determination. Taking the mean value of INR, among the 85 patients who have INR determination at least once, 49(57.6%) patients had INR value within the therapeutic range while 20(23.5%) patients had undertherapeutic INR value and 16(18.8%) patients had supratherapeutic INR value. Among patients taking OAC, 6(6.6%) patients reported major bleeding. Other medication taken includes diuretics in166 (64.8%) patients, b-blockers in 127(49.6%) patients, digoxin in 34(13.3%) patients and ACEI/ARB in 22(8.6%) patients (**Table 5).**

Table 5: Medical management in Patients With CRVHD, TASH ,Addis Ababa, 2020 (n=256)

Charctestics	number	percentage
BP adherence		
Not taking	34	13.3
12 times annually (not missed any)	132	51.6
10-11 times annually (missed <3 times)	27	10.5
<10 times annually (missed ≥3 times)	63	24.6
Average 1 year adherence	73.58%	
At risk of thromboembolism/indication	96	37.5
A.fib	73	76
a.flutter	1	1
LA thrombus +a.fib	7	7.3
mechanical valve	12	12.5
mechanical valve + a.fib	3	3.1
On OAC	91	94.8
Warfarin	90	98.9
NOAC	1	1.1
INR(n=90)		
Not determined	5	5.6
Determined once	7	7.8
Determined twice	22	24.4
Determine three times	56	62.2
INR range(n=85)		
therapeutic	49	57.6
undertherapeutic	20	23.5
supratherapeutic	16	18.8
Bleeding	6	6.6
Other medication		
Diuretics	166	64.8
BB	127	49.6

ACEI/ARB	22	8.6
Digoxin	34	13.3

5.4.2 Percutaneous or surgical interventions

Among 213 patients for whom percutaneous or surgical interventions was considered/indicated, intervention done for only 38(17.8%) patients. whereas 175(82.2%) were not, mostly for limited access (171(97.7%) patients were on waiting list while 4(2.3%) patients were unfit for intervention. Out of these percutaneous valvuloplasty (all are MV) was done for 20 patients while open valve surgery done for the remaining 18 patients (single valve surgery for 11 patients and two valve surgery for 7 patients). Most of the procedures done in public hospital in Ethiopia (31, 81.6%) followed by centers outside Ethiopia (6, 15.8%) and private center in Ethiopia (1, 2.6%) (**Table 6).**

Table 6: Percutaneous or surgical interventions in Patients With CRVHD, TASH ,Addis Ababa, 2020 (n=256)

Charctestics	number	percentage
Considered for valve intervention/indicated	213	83.2
Intervention done(n=213)	38	17.8
Percutaneous valvuloplasty	20	52.6
Open valve surgery	18	47.4
Centers where the procedures were done		
Public Hospital in Ethiopia	31	
Private Hospital in Ethiopia	1	
Outside Ethiopia	6	
Not intervened despite indicated(n=175)		
Unfit	4	**2.3**
Waiting list	171	**97.7**
Waiting time mean	2.526 (0-10 years)	

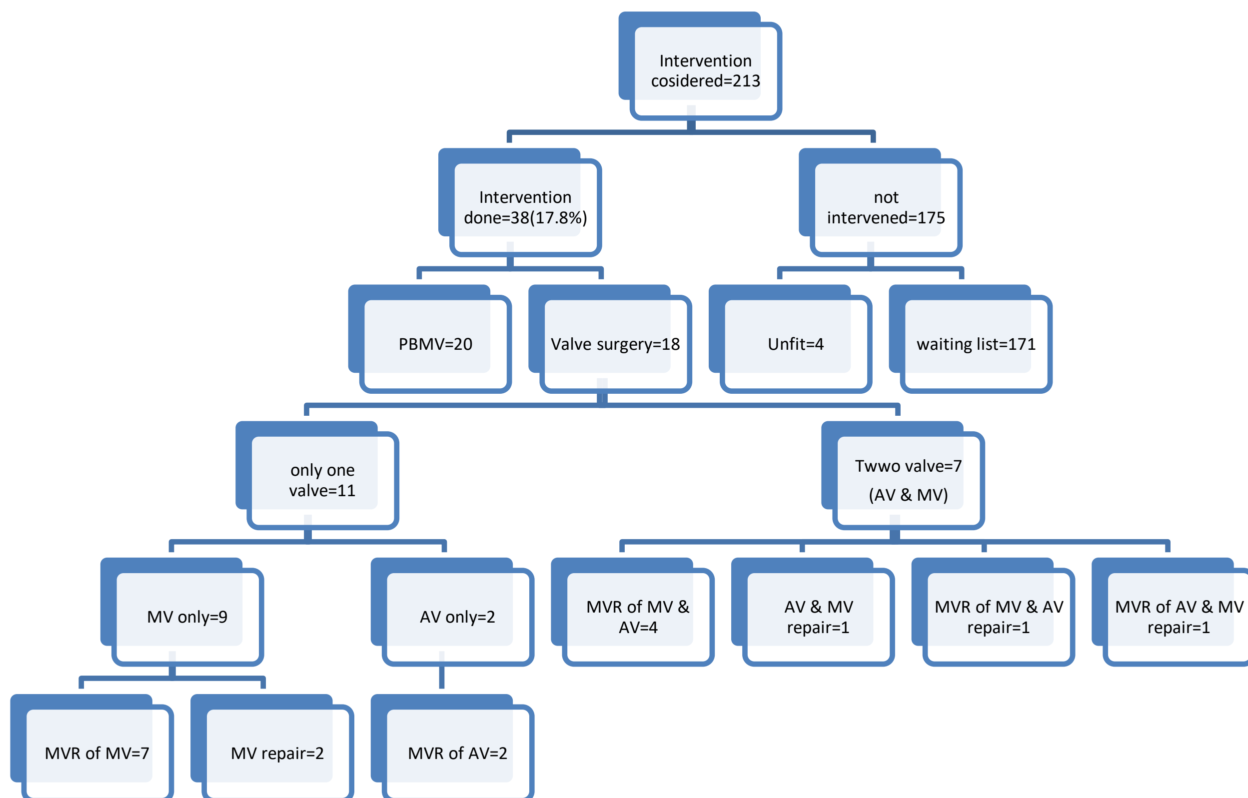

Figure 3: Percutaneous/open valve intervention collected from Adult cardiology clinic, TASH 2020 Abbreviations: MV, mitral valve; TV, tricuspid value; AV, aortic valve; MVR, Mechanical valve replacement.

5.4.3 Determinants of cardiovascular complications

On bivariate logistic regression, the presence of advanced heart failure was found significantly associated with MS(COR, 2.150; 95% CI, 1.168 to 3.956; P=0.014),, AR(COR,1.90; 95% CI,1.112 to 3.250; P=0.019), TR(COR, 3.258; 95% CI, 1.896 to 5.598; P=0.00001), RVSD(COR, 4.456; 95% CI,2.111 to 9.404; P=0.00008), and LA enlargement(COR, 1.069; 95% CI, 1.041 to 1.098; P=0.000). Although female subjects outnumbered male subjects in the study population, no sex difference in prevalence of advanced heart failure was noted. (**Table 7**)

Multivariate logistic regression revealed that RVSD (AOR, 2.346; 95% CI, 0.999 to 5.508; P=0.050) and LA enlargement (AOR, 1.044; 95% CI, 1.008 to 1.081; P=0.016) are independent determinant of having advance heart failure. **(Table 8)**

Table 7: Bivariate logistic regression showing the association of independent variables and presence of advanced heart failure on RHD patients, Tikur Anbessa specialized Hospital of year 2020 (n=256)

Variable	Frequency(%)	COR(95%, CI)	P-value
MS(n=233)	170(73%)	2.150(1.168 - 3.956)	0.014
AR(n=233)	138(59.2%)	1.901(1.112 - 3.250)	0.019
TR(n=233)	121(51.9%)	3.258(1.896 - 5.598)	0.00001
MR(n=233)	178(76.4%)	0.841(0.457 - 1.551)	0.580
AS(n=233)	36(15.5%)	0.693(0.340 1.413)	0.313
LA size mean (n=233)	47.5	1.069(1.041 - 1.098)	0.000
RVSD(n=233)	42(18%)	4.456(2.111 - 9.404)	0.00008
Intervention done(n=256)	38(14.84%)	1.836(0.881 - 3.826)	0.105

Table 8: Multivariate logistic regression showing the association of independent variables and presence of advanced heart failure on RHD patients, Tikur Anbessa specialized Hospital of year 2020 (n=256)

Variable	Frequency (%)	COR(95%, CI)	AOR(95%, CI)	P-value
MS(n=233)	170(73%)	2.150(1.168 - 3.956)	0.969(0.463-2.031)	0.935
AR(n=233)	138(59.2%)	1.901(1.112 - 3.250)	0.623(0.336-1.156)	0.133
TR(n=233)	121(51.9%)	3.258(1.896 - 5.598)	0.484(0.262-0.895)	0.021
MR(n=233)	178(76.4%)	0.841(0.457 - 1.551)	1.037(.516-2.083)	0.919
AS(n=233)	36(15.5%)	0.693(0.340 1.413)	0.570(.246-1.318)	0.189
LA size mean (n=233)	47.5	1.069(1.041 - 1.098)	1.044(1.008-1.081)	0.016
RVSD(n=233)	42(18%)	4.456(2.111 - 9.404)	2.346(0.999-5.508)	0.050
Intervention done(n=256)	38(14.84%)	1.836(0.881 - 3.826)	1.751(.508-6.034)	0.375

6. Discussion

Although the huge burden of RHD in Ethiopia, only few studies done to characterize and the existing burden. In one retrospective cardiovascular death analysis at TASH, between 1995 and 2001, RHD patients found to have combined valve lesions early and more aggressive course (26). Prospective study done on 114 (female=66%) patients between January 1994 and January 1995 at Gondar College of Medical Sciences Teaching Hospital described valvular and clinical patterns of RHD patients(40). The multinational REMEDY (Global Rheumatic Heart Disease Registry) registry from 25 hospitals in 12 African countries including Ethiopia, Yemen and India described the pattern of RHD and its management gaps but data was analyzed as a whole and we couldn't find separate data regarding current echocardiographic Pattern and gaps in managing RHD in Ethiopia (20).

This study revealed many finding. First, the majority of RHD patients were females (75%), young (median age 30 year), high rate of unemployment (50.4%) and 23.4% of patients had not completed even primary school. Second, the most common valvular lesion was MR (76.4%) and mitral valve was involved in 94.8% of patients and majority of patients(75.5%) had combined valvular involvement. Third, the majority of patients had severe/very sever valvular heart disease(78.1%) that was associated with pulmonary hypertension(69.5%), chamber dilatation, symptoms of advanced heart failure(53.6%) and atrial fibrillation(32.4%). Fourth, adherence rate to secondary antibiotic prophylaxis was low (average: 73.58%). Fifth, the overall use of OACs in patients identified to be at high risk for thromboembolic events was high(94.8%) but, the quality of average anti-coagulation control was poor, with only 57.6% of these patients had INR value within the therapeutic range while 23.5% patients had undertherapeutic INR value and 18.8% patients had supratherapeutic INR value. Finally, although 83.2% of patients was considered/indicated for percutaneous or surgical interventions, intervention done only for 17.8% of these patients.

Rheumatic fever (RF) and rheumatic heart disease (RHD) are nonsuppurative complications of Group A streptococcal pharyngitis due to a delayed immune response. Rheumatic heart disease and its complications reduce quality of life, result in loss of income because of poor attendance at work, and, among children, poor scholastic performance and death at young age(25, 26). In this study, the majority (60.9%) of the patients were age 20-49years and the median age of

patients was 30 years which is comparably equal to reported in the REMEDY registry and VALVAFRIC study (18, 20) but higher than reported in study done from January 1994 and January 1995 at Gondar College of Medical Sciences Teaching Hospital which was 23 years (40). This could be due to early diagnosis and increased survival or the previous study also included pediatric age group while the current study conducted among patients following at adult cardiac clinic (starting from age 13 years).

Female predominance hypothesized in RHD due to greater exposure to group A beta hemolytic streptococcal and lack of access to medical care which has been demonstrated in most of the previous studies (18, 20, 38, 41). This study strengthened this female female preponderance of RHD in female (75%). RHD affects people from the rural area than the urban area (41). But, in this study the majority of patients are from urban area (75.8%). This could be explained by the study period was the time of COVID-19 pandemic during which the patient flow from rural area to the center (TASH) significantly decreased.

Like the previous studies including REMEDY and VALVAFRIC study, in this study the predominant valvular lesion was mitral regurgitation (76.4%). The result of this study also demonstrated that mitral valve and aortic valve was affected in 94.8% and 60.9% of patients respectively while combined mitral valve disease and combined mitral and aortic disease was seen in 54.5% and 55.8% of patients respectively.

In this study the majority of the patients had severe/very sever valvular dysfunction (78.1%) which is higher than observed in other studies(20,41). This may be due to late diagnosis or rapid progression of disease in our setup. The other possibility is TASH is the only tertiary care center in the country where percutaneous and surgical valvular intervention cold be done and patients may be referred near to advanced stage for such intervention. The presence of severe/very sever valvular disease might be the possible explanation for high prevalence of pulmonary hypertension (69.5%), chamber dilatation, symptoms of advanced heart failure (53.6%) and atrial fibrillation (32.4%) which is higher than the pattern seen in REMEDY(advanced heart failure symptom:13.9%-27.6%,pulmonary hypertension:19%-29.9%, and atrial fibrillation:17.9%-

22.7%) and in a prospective 6 year registry study in India (advanced heart failure:15.7%, pulmonary hypertension:30.5%, and atrial fibrillation: 24.4%)(20, 41).

It is well recognized that heart failure is a common cause of disability among patients with RHD (20). In this study majority of patients (92.5%) were symptomatic at some point since the diagnosis while symptoms of advanced heart failure (NYHA functional classes III and IV) was reported in 53.6% of patients which is higher than the result of previous studies(Table 4).

On bivariate regression the presence of advanced heart failure was found significantly associated with MS(COR, 2.150; 95% CI, 1.168 to 3.956; P=0.014),, AR(COR,1.90; 95% CI,1.112 to 3.250; P=0.019), TR(COR, 3.258; 95% CI, 1.896 to 5.598; P=0.00001), RVSD(COR, 4.456; 95% CI,2.111 to 9.404; P=0.00008), and LA enlargement(COR, 1.069; 95% CI, 1.041 to 1.098; P=0.000). but, when independent variables adjusted only RVSD (AOR, 2.346; 95% CI, 0.999 to 5.508; P=0.050) and LA enlargement (AOR, 1.044; 95% CI, 1.008 to 1.081; P=0.016) was independent determinant of having advance heart failure. Although female subjects outnumbered male subjects in the study population, no sex difference in prevalence of advanced heart failure was noted. (Table 7 & Table 8)

Much of the morbidity and mortality due to RHD can be prevented by existing therapies. Secondary prophylaxis with long-acting penicillin reduces the recurrence of episodes of acute rheumatic fever and RHD progression(10,11,12). In this study, overall 13.3% patients were not taking secondary antibiotic prophylaxis while 86.7% patients were taking it which is much better than seen in REMEDY(45.2%), prospective 6 year registery study in india(28.5%) and cross-sectional study done at the Adult Cardiac Clinic of Tikur Anbessa Specialized Hospital (TASH) on 2020 (76.6%). This difference might be due to the variability of indication depending age, duration of illness and presence or absence of prosthetic valve. In this study, including patients who were not taking secondary antibiotic prophylaxis average annual adherence was 73.58%(Table 5). However, only 62.1% of patients had good adherence (taking ≥80% of their prescribed monthly BPG prophylaxis dose) which was 69.7% in cross-sectional study done at the Adult Cardiac Clinic of Tikur Anbessa Specialized Hospital (TASH) on 2020 and 55.2% in a

cross-sectional study conducted at cardiac clinic of Jimma Medical Center (JMC), Ethiopia, from June 1-September 30, 2018 (21,42).

Thromboembolic events are among the common complications of RHD and are well known cause of morbidity and mortality in RHD patients (18, 20, 38, 41). Thromboembolic events were reported 4% in VALVAFRIC study(18). In prospective 6 year registry India 3.9% and 4.1% patients had stroke and peripheral embolism respectively (41). The REMEDY study also reported Stroke and peripheral embolism in the range from 3.8% to 14.5% and 0.2% to 2.2%, respectively, across different income groups of developing countries (20). The present study revealed that 5.5% and 0.4% patients had stroke and peripheral embolism respectively (Table 4). To decrease this risk OAC are recommended in RHD patients who had intracardiacbthrombus, mechanical valve, MS with atrial fibrilation and based on CHA2DS2-VASc score in patients with AF and native aortic valve disease, tricuspid valve disease, or MR(14).

In this study, among patients identified to be at high risk for stroke and peripheral embolism 94.8% patients were receiving OAC which was hgher than reported by REMEDY study (70%) and prospective 6 year registry in India(77.8%)(20,41). However, the number of patients who didn't have INR determination with appropriate time interval was high (Table 5). Although better than reported from REMEDY study (25%), INR control was poor in which only 57.6% of patients having therapeutic level INR among patients who had INR determination at least once. This difference could be due to higher proportion of patients have urban background but still there is huge gap that should be assessed with further study and including decentralizing care and studying other OAC that doesn't require INR follow-up(15, 20).

The definitive treatment option valvular dysfunction RHD is either balloon valvuloplasty or valve replacement/repair. In this study, despite majority (83.2%) of patients were considered/indicated, intervention was done only for 17.8% of patients. Even though this finding is higher than reported from REMEDY and VALVAFRIC study, it is far from the existing demand (18,20). There was significant urban bias in accessing percutaneous/surgical valve intervention. Patients who had urban background had 7.2 times getting the chance than patients who had rural background (COR, 7.200; 95% CI, 1.670 to 31.039; P=0.008). This finding reinforced the finding reported from review of cardiac surgery for VHD cases at TASH in Ethiopia over a 30 year period, from 1983 to 2013(43).

7. Strength & Limitation of the study

7.1 Strength of the Study

- Studied the disease which didn't get appropriate attention regarding primary and secondary prevention as well as its treatment in spite of existing burden was high.
- It was the first study done in Ethiopia to asses both pattern and management of RHD patents.

7.2 Limitations of the study

- It was difficult to get ECG and information regarding arrhythmia was gathered from what documented on patient's chart or electronic medical record.
- The study conducted with convenience sampling technique in single tertiary center which might limit generalizability of the findings for all RHD patients in Ethiopia or elsewhere around the world.
- The study period was the time of COVID-19 pandemic. During that time patient most of patients were addressed with phone clinic and flow was significantly reduced.
- The design of the study was cross sectional and no follow-up assessment done after first contact which will affect the reliability observed association of independent variables on complication (advance heart failure)

8. Conclusion

RHD is a disease of young and middle-aged population affecting predominantly females and it is complicated early with severe valve lesion, advanced heart failure, pulmonary hypertension, atrial fibrillation and thromboembolism. There are gaps in the use of secondary antibiotics prophylaxis, INR control. There is limited and biased access to percutaneous/surgical intervention emphasizing the importance of primary prevention and early secondary prevention strategy to avoid progression to severe RHD and to delay complications.

9. Recommendation

Based on the study the following recommendations are forwarded.

- Few studies done in Ethiopia are single institution based studies with small sample size, so large prospective multi-center studies are necessary to validate the current findings
- The fact that RHD is the major contributor cause of cardiac disease, conducting high scale population-based studies to formulate informed policies and programs for prevention and control of RHD.
- The burden of the disease is high so that it is the high time give attention for establishment and expansion of centers that will provide the care of such patients including surgical intervention.
- The frequency of INR monitoring is far from the usual recommendation and it will be the time to strengthen laboratory access and decentralize care.

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11. Annexes

11.1 Declaration

I, the undersigned, declare that this postgraduate thesis is my original work, has not been presented for a degree in this or any other university and that all sources of material used for the thesis have been duly acknowledged.

Postgraduate Candidate: Tadesse Getnet (MD, Internal Medicine Resident)

Signature: ………………………….

Date of Submission: December 29, 2020

This thesis has been submitted with my approval as advisor.

Advisor: Dejuma Yadeta (MD, consultant Internist, cardiologist)

Signature: ………………………….

11.2 Respondents information sheet and consent form English Version

Hello, how are you?

My name is ________________. I am data collector on behalf of Dr Tadesse Getnet , internal medicine resident, in AAU, college of health sciences, internal medicine department, who conduct this study. I kindly request you to give me your attention to explain about the study and being selected as the study participant.

The study title: Rheumatic heart disease pattern and management gaps at Tikur Anbessa Specialized Hospital, Addis Ababa, Ethiopia.

The objective of the study: To describe characteristics and assess management gaps of RHD patients at TASH.

Importance of the study: The findings of this study can be of paramount importance for the TASH health planner, Minster of health and policy makers to plan intervention programs to prevent RHD and improve management of RHD patients. Your cooperation and willingness for the interview is very helpful in identifying the problems related to the issue.

Risks: Participating in this study has no mental or physical risk and it only takes 15 minutes.

Confidentiality: The information you provide for us will be confidential. Your participation in the study will be totally based on your willingness. You have the right not to participate from the beginning, or stop any time after starting participation. You will not be forced to respond to the information you do not know. Your name will not be included in the information. But the information that you will give us is quite useful to achieve the objective of the study.

So, I kindly request you to ask some questions. Would mind if I take some minutes with you? It may take about 15minutes. Thus, I kindly request you to participate in genuinely answering the interview.

Thank you!

Are you willing to participate in the study? A- Yes B - No

Sign: __________________ Date: __________________

NB: If you have any questions about the study, the name and contact information of the principal investigator (PI) is given below.

Name of PI: Dr. Tadesse Getnet Tel: +251912110705 E- mail address: tadekebron@gmail.com

Interviewer's: name _________________signature _______________

Date of interview _______ date ________month/2020 G. C.

Checked on __________date _________month/2020 G.C

Complete_____________ Incomplete ___________other (specify) ________________

11.3 Respondents information sheet and consent form Amharic Version

የመረጃ እና የስምምነት ቅጽ

ሰላም፣ እንደምን አሉ?

ስሜ _______________ይባላል።እዚህ የተገኘሁት በአዲስ አበባ ዩኒቨርሲቲ ህክምናና ጤና ሳይንስ ኮሌጅ የውስጥ ደዌ ህክምና ትምህርት ክፍል የስፔሻላይዜሽን ተማሪ የሆነውን ዶ/ር ታደሰ ጌትነት ወክየ መረጃ ለመሰብሰብ ነው። ስለጥናቱ ገለጻ ሳደርግለወት በአጽንኦት እንዲያዳምጡኝ በትህትና እጠይቃለው።

የጥናቱ ዓላማ፡ በጥቁር አንበሳ ስፔሻላይዝድ ሆስፒታል ውስጥ የሪውማቲክ ልብ ህመም (RHD) ህመምተኞች ሁኔታና የህክምና ክፍተቶችን ለመዳሰስ።

የጥናቱ ጠቀሜታ፡ የዚህ ጥናት ግኝቶች የሪውማቲክ ልብ ህመምን (RHD) ለመከላከል እና የ RHD ህመምተኞቹን አያያዝ ለማሻሻል እና የህክምና መርሃ ግብሮችን ለማቀድ ለጥቁር አንበሳ ሆስፒታል፣ለጤና ሚኒስቴር እና ለፖሊሲ አውጭዎች በጣም አስፈላጊ ግብዓት ይሆናል። ለቃለ መጠይቁ የሚያደርጉት ትብብር እና ፈቃደኛነት ከጉዳዩ ጋር የተዛመዱ ችግሮችን ለመለየት ይረዳል ።

ከጥናቱ ጋር የተያያዘ ጉዳት፡ በዚህ ጥናት ውስጥ መካተት የአእምሮም ሆነ አካላዊ ጉዳት የለውም። መጠይቁ 15 ደቂቃዎችን ብቻ ይወስዳል።

ምስጢራዊነት፡ ለእኛ የሚሰጡን መረጃ በሚስጥር የተጠበቀ ይሆናል ። በጥናቱ ውስጥ ያለዎት ተሳትፎ ሙሉ በሙሉ በፍላጎትዎ ላይ የተመሠረተ ይሆናል ። ከመጀመሪያው ላለመሳተፍ መብት አለዎት ወይም ተሳትፎ ከጀመሩ በኋላ በማንኛውም ጊዜ ማቆም ይችላሉ ። ለማያውቁት መረጃ ምላሽ እንዲሰጡ አይገደዱም ። ስመዎት በመረጃው ውስጥ አይካተትም። ነገር ግን የሚሰጡን መረጃ የጥናቱን ዓላማ ለማሳካት በጣም ጠቃሚ ነው ።

ስለዚህ አንዳንድ ጥያቄዎችን እንድጠይቀዎት በትህትና እጠይቃለሁ ። መጠይቁ ወደ 15 ደቂቃዎች ያህል ሊወስድ ይችላል። ስለሆነም በቃለ መጠይቁ በእውነቱ መልስ እንዲሰጡ በትህትና እጠይቃለሁ ።

አመሰግናለሁ!

በጥናቱ ለመሳተፍ ፈቃደኛ ነዎት? ሀ- አዎ ለ - የለም

ፊርማ __________________ ቀን: __________________

ማስታዎሻ:

ስለ ጥናቱ ተጨማሪ ጥያቄ ካለዎት እና አጥኚዉን መጠየቅ/ መግኛት ከፈለጉ፤

የአጥኚዉ ስም: ዶ/ር ታደሰ ጌትነት

ስልክ: 251912110705

የኢሜል አድራሻ: tadekebron@gmail.com

ቃለ መጠይቁን ያከናወነው ስም __________________ ፊርማ __________________

ቃለ መጠይቁ የተካሄደበት _________ ቀን _________ ወር / 2020 እ.ኤ.አ.

የተረጋገጠበት ቀን _________ቀን _________ወር / 2020 እ.ኤ.አ.

የተሟላ _____________ ያልተሟላ _______________ሌላ (ይግለጹ)_________________

11.4 Data collection format

Date_________________

Card number (MRN) _________________I-care number_________________

1. Baseline demographic characteristics
   1.1. Age (in years)_________________
   1.2. Sex A. Male B. Female
   1.3. Residence A. Urban B. Rural
   1.4. Educational Level
      A. Illiterate
      B. Can read/write
      C. Primary education
      D. Secondary education
      E. Higher level education(College/University)
   1.5. Occupation
      A. Daily worker
      B. Farming
      C. Private work
      D. Government employee
      E. Student
      F. House wife
      G. Jobless
      H. Others (specify) _______________
2. Clinical data
   2.1. Duration of cardiac illness in years_______________
   2.2. Number of years since the medical discovery of valve disease_______________
   2.3. The highest degree of symptoms (NYHA functional status) since your illness
      A. I -no symptom
      B. II- symptom while climbing stairs
      C. III - symptom while walking short distance
      D. IV- symptom at rest
   2.4. Number of hospitalization due to cardiac cause
      In the last one year_______________
      Since time of diagnosis_______________
   2.5. Presence of arrhythmia? A. Yes ___B. No__
   2.6. If the answer for question number 2.5 is 'Yes', what type of arrhythmia?
      A. Atrial fibrillation
      B. Atrial Flutter
      C. Others (specify)_______________
   2.7. Thromboembolic event
      A. Stroke
      B. Peripheral embolism

3. Echocardiographic description of valvular lesion
   3.1. Mitral valve

A. MS ______________Severity______________
B. MR _______________Severity _______________
3.2. Aortic valve
A. AS _______________Severity______________
B. AR _______________Severity_______________
3.3. Tricuspid valve
A. TS _______________Severity _______________
B. TR _______________Severity _______________
3.4. Pulmonic valve
A. PS _______________Severity_______________
B. PR _______________Severity______________
4. Other echocardiographic data
4.1. Left atrium size _______________mm
4.2. LV diastolic diameter _______________mm
4.3. LV end-systolic diameter _______________mm
4.4. LV ejection fraction______________%
4.5. RV dilatation (Mid right ventricular Cavity _______________mm.)
A. No B. Yes
4.6. Tricuspid annular plane systolic excursion (TAPSE) _____________mm
4.7. Left atrium / left atrial appendage thrombus A. Yes B. No
4.8. Pulmonary hypertension (systolic PA pressure ______________mmHg)
A. No B. Yes 1. Mild 2. Moderate 3. Severe
5. Management
5.1. How much the dose of prophylaxis antibiotics received out of 12 required injections in the last one year ___________/12
5.2. Anticoagulant treatment indicated?
A. NO
B. Yes
5.3. If the answer for Q.No. 5.2. is ‘B’, is the patient taking oral anticoagulant?
A. No
B. Yes
5.4. If the answer for Q.No. 5.3. is ‘A’, what was the reason
A. Not ordered
B. Refused
C. Contraindicated
D. Other reason_______________
5.5. If the answer for Q.No. 5.3. is ‘B’
A. Specify the indication _______________
B. Specify the drug _______________
C. What is the value of recent 3 INR measurements if the patient is taking warfarin? _______/________/_____________
D. Major bleeding 1. Yes 2. No
5.6. Other medical managements
A. Diuretics (specify it) _______________
B. Beta-blockers
C. ACE-I/ARB
D. Digoxin
E. Others (specify) _______________

5.7. Percutaneous or surgical interventions indicated?

A. No

B. Yes

5.8. If the answer for Q.No 5.7 is 'B', percutaneous or surgical interventions done?

A. No

B. Yes

5.9. If the answer for Q.No 5.8 is 'A', what was the reason?

A. Refused

B. Not fit for intervention

C. Waiting (How long after opted for valve surgery? _______________Year)

D. Other reason_______________

5.10. If the answer for Q.No. 5.8 is 'B',

1. Where was the intervention done?
    A. Public Hospital in Ethiopia
    B. Private Hospital in Ethiopia
    C. Outside Ethiopia
2. Type of intervention done?
    A. Percutaneous valvotomy
    B. Open heart surgery
3. What is the type of intervention and valve intervened?
    A. Percutaneous valvotomy of _______________valve
    B. Valve repair of _____________________________valve
    C. Mechanical valve of ______________________________valve
    D. Bio-prosthetic valve of _____________________________valve
4. Is there any post-procedure complication?

A. Prosthetic dehiscence? 1. Yes 2. No

B. Prosthetic dysfunction?

1. No.

2. Yes. A. Regurgitation B. Stenosis

C. Prosthetic thrombus 1. Yes 2. No

D. Prosthesis Endocarditis? 1. Yes 2. No

E. Post-op heart failure? 1. Yes 2. No

F. Others (specify)_____________________