



Saint Paul Hospital's Millennium Medical College

Magnitude and outcome of glomerular disease among patients admitted to Saint Paul Hospital's Millennium Medical College

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A research proposal to be submitted to Saint Paul Hospital's Millennium Medical College, Department of Internal Medicine, Nephrology Unit in partial fulfillment of the requirement for the sub-specialty certificate in Nephrology .

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Abstract

Introduction: Chronic kidney disease (CKD) has a high global prevalence and incurs high burden to the healthcare system worldwide. In SSA chronic GN IS the commonest cause of CKD. In Ethiopia acute GN is commonest cause among patients requiring hemodialysis. In Ethiopia there are no studies on glomerular disease.

Objective: Magnitude and outcome of glomerular disease among patients admitted to Saint Paul Hospital's Millennium Medical College

Methods: A cross sectional card review was used to assess the prevalence and outcome of glomerular disease among patients admitted with AKI from September 2016-september 2017

Result Glomerular disease accounts for 33% of patients admitted with AKI.86.4% are under age of 45years.68.5% presented with $cr > 3mg/dl$.HD was provided in 40.9%.renal biopsy was done in only 34.1% of patients. Treatment response was seen only in 58.5% of patients

Conclusion Glomerular disease accounts for significant proportion of patients admitted with AKI. It is mainly affects young people. Diagnosis and work up is inadequate in most patients contributing to poor outcome.

Acknowledgement

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List of acronyms

GN- Glomerulonephritis

RPGN- Rapidly proliferative glomerulonephritis

CKD- Chronic Kidney Disease

AKI – Acute kidney Injury

SPHMMC – Saint Paul Hospital's Millennium Medical College

RRT – Renal Replacement Therapy

Chapter One: Introduction

1. BACKGROUND

1.1. INTRODUCTION

Chronic kidney disease (CKD) has a high global prevalence between 11 to 13%. It also incurs high burden to the healthcare system worldwide (1). End-stage renal disease (ESRD) is a significant public health issue worldwide, and this problem is compounded by limited access to renal replacement therapy (RRT) in developing countries. It is estimated the number of patients needing RRT to be around 4.902 million and the largest treatment gaps needing but not receiving RRT is seen in low-income countries, particularly Asia (1.907 million people) and Africa (432,000 people) (2).

There are regional disparities in the etiology of ESRD in the world. Diabetes mellitus and hypertension are the major causes of ESRD in developed countries while in sub-Saharan Africa chronic glomerulonephritis (GN) accounts for a high proportion of ESRD patients (3). Glomerular diseases remain poorly characterized in sub-Saharan Africa due to declining renal biopsy rates and consequent paucity of data on pathologic patterns of key renal diseases.

In Ethiopia although there is limited data Acute Glomerulonephritis (diagnosed through clinical means) was found to be a common cause of AKI among patients requiring dialysis (4).

1.2 Statement of the problem

Chronic kidney disease (CKD) has a high global prevalence and incurs high burden to the healthcare system worldwide. In SSA chronic GN is the commonest cause of CKD (4). In Ethiopia acute GN is commonest cause among patients requiring hemodialysis. The gloomy outlook of CKD and the limited access to RRT makes prevention the only viable option in SSA and particularly in Ethiopia. In Ethiopia there are no studies on glomerular disease. Identifying the magnitude, risk factor and pattern of Glomerular disease help us plan future prospective trials and optimize diagnostic modality, treatment options and plan preventive strategies.

1.3 Significance of this study

The purpose of this study is to know the magnitude of glomerular disease among patients admitted with renal disease. It will try to answer the risk factor associated and pattern of glomerular disease .it will try to see how clinical definition of glomerulonephritis and biopsy correlate. It will try to identify what are strong predictors of GN these will be a great input for policy makers to design protocols in resource limited setup and prevention strategies. Furthermore this study can be used as the reference for further studies in the field and helps as the source of data.

Chapter Two: Literature Review

Chronic kidney disease (CKD) has a high global prevalence between 11 to 13%. It also incurs high burden to the healthcare system worldwide (1). End-stage renal disease (ESRD) is a significant public health issue worldwide, and this problem is compounded by limited access to renal replacement therapy (RRT) in developing countries. In sub-Saharan Africa, CKD is a substantial health burden with risk factors that include communicable and non-communicable diseases. (2) It is estimated the number of patients needing RRT to be around 4.902 million and the largest treatment gaps needing but not receiving RRT is seen in low-income countries, particularly Asia (1.907 million people and Africa 432,000 people) (3).

There are regional disparities in the etiology of ESRD in the world. Diabetes mellitus and hypertension are the major causes of ESRD in developed countries while in sub-Saharan Africa chronic glomerulonephritis (GN) accounts for a high proportion of ESRD patients. (4) Glomerular diseases remain poorly characterized in sub-Saharan Africa due to declining renal biopsy rates and consequent paucity of data on pathologic patterns of key renal diseases. In Ethiopia although there is limited data Acute Glomerulonephritis (diagnosed through clinical means) was found to be a common cause of AKI among patients requiring dialysis. (5)

Kidney disease in Africa affects mainly young individuals in their economically productive years and patients present late whereas in developing world it is seen with advanced age (6,7)

According to clinical presentation glomerular disease is classified into clinical syndromes. Nephrotic syndrome is defined as urine protein excretion > 3.5 g/24 h, Hypoalbuminemia < 3.5 g/dl, edema, hypercholesterolemia and lipiduria. The ANS as presence of hematuria, proteinuria, edema, hypertension and reduced estimated glomerular filtration rate and AUA as non-nephrotic range proteinuria (with or without microscopic hematuria). Rapidly progressive glomerulonephritis renal failure over days to weeks proteinuria: usually < 3 g/day hematuria: red cell casts. AKI was defined as acute presentation associated with impaired renal function and CKD as persistently increased serum creatinine for > 3 months and small echogenic kidneys on abdominal U/S. (8).

The pattern of renal disease differs in sub Saharan Africa the commonest indication for renal biopsy is nephrotic syndrome. Among primary glomerular disease minimal change disease, Focal segmental glomerulosclerosis, MCGN followed by crescentic GN and IgA nephropathy Among causes for secondary GN lupus nephritis and Hepatitis virus associated GN account for the majority of cases.(9).In SSA a triad genetic, environmental and climatic factors predispose to GN.(10) Among causes of primary Glomerular disease FSGS have high prevalence in blacks and HIVAN and lupus are seen in high proportion in secondary glomerular disease. *APOL1* variants conferred seventeen fold higher odds for focal segmental glomerulosclerosis (FSGS) and twenty-nine-fold higher odds for HIV-associated nephropathy (HIVAN).(11) *APOL1* variants are common among African and absent in Europeans. The bio ecological environment also contributes to infectious disease associated Glomerular disease in Africa. The poor living condition and low hygiene may promote TH1 type of response and predispose to proliferative forms of lupus in low socioeconomic environment. (13)Improvement of national economy has been shown to reduce the incidence of glomerulonephritis in several countries, as in Egypt, Pakistan (10).

Chapter Three: Objective

General objective

To assess the pattern and magnitude of Glomerular disease among patients admitted in Saint Paul hospital with renal disorder

Specific objective

To access the need for renal replacement therapy glomerular disease among admitted in SPHMMC

Treatment outcome of patients with glomerular disease among admitted in SPHMMC

Clinical and biopsy correlation glomerular disease among admitted in SPHMMC

Pattern of glomerular disease

Chapter Four: Study Design and Methods

Methods and Materials

4.1 Study Area

The study will be conducted in St Paul hospital one of the largest public hospital in the country .St Paul Hospital was built by Emperor Haile Selassie in 1961 .It is public hospital primarily serves those unable to afford care elsewhere ,providing service free of charge to 75 % of the its patient .An estimated 1200 clinical and non-clinical staff provide care to approximately 200,000 people each year and a catchment population of more than 5 million .St Paul receive referral from all over the country and is under guidance of Ethiopian Ministry of Health .In 2007 ,St Paul added a medical college ; St Paul hospital millennium medical college ,with current enrollment of 250 students and 80 residents.

Our hospital has established the first hemodialysis unit in government hospital giving hemodialysis for patients with acute kidney injury and transplant candidates since august 2013.our hospital have also established the first renal transplant center since 2015 and have done more than 80 renal transplantations. Our hospital have around 45 beds for inpatient admissions and 32 HD machines.

Study Design

A cross sectional card review will be used to assess the prevalence and pattern of glomerular disease among patients admitted with AKI at St Paul hospital millennium medical college internal medicine ward.

Source Population

All patients admitted in internal medicine ward with renal disease AKI from September 2016 to September 2017 at St Paul Hospital millennium medical collage

Study Population

Patient with the at St Paul Hospital millennium medical collage with glomerular disease

Inclusion Criteria

1. Age >15years
2. All patients admitted in internal medicine ward with clinical diagnosis of glomerular disease by clinical criteria or biopsy proven GN

Exclusion Criteria

1. Age < 15 years
2. Pregnant women
3. Patient with CKD (shrunken kidneys,Hx of elevated Cr more than 03 month)

Sample Size Determination

Sample size calculation for this study is performed using the single population proportion formula.

Equation 1. Sample Size Calculation for Single Population Proportion

$$n = \frac{(Z_{\alpha/2})^2 \times P (1 - P)}{w^2}$$

Where,

P = proportion of patients with glomerular disease among admitted patients with AKI

W = margin of error

Z = the probability with which the observed change would have occurred by chance for a given confidence interval.

The total number of AKI patients admitted at SPHMMC internal medicine ward between September 2016 to September 2017 is 100 and the prevalence of patients with glomerular disease to be around 20% at SPHMMC , 5% margin of error, 95% confidence interval, the calculated total number patients 72

Operational definitions

Acute kidney injury (AKI): elevated serum creatinine 1.5 times above the upper normal limit of the laboratory range OR urine output <0.5 ml/kg/h for 6–12 hours OR serum creatinine change by 0.3 mg/dL from baseline

Chronic kidney disease (CKD): evidence of laboratory or imaging evidence of kidney disease for >3 months OR radiologic evidence of renal osteodystrophy OR small bilateral kidneys on imaging

End-stage renal disease (ESRD): final stage of CKD defined by loss of kidney function defined estimated glomerular filtration rate <10 ml/min/m² using any of the internationally validated formulas

Glomerulonephritis (GN)

Possible GN: clinical presentation with 2 or more of the following

1. Body swelling
2. Hypertension (BP $\geq 140/90$)
3. Oliguria (urine output <0.5 ml/kg/hour for 6-12 hours)
4. Gross hematuria (cola colored or red urine)

Probable GN: possible GN with either of the following

1. Urine dipstick positive for hematuria and/or proteinuria
2. urine microscopy showing many RBC and/or dysmorphic RBC
3. urine microscopy showing RBC casts
4. 24 hour urine protein >500 mg with hematuria or >2 g without hematuria

Definitive GN: kidney biopsy evidence of glomerular injury

Acute GN: GN with onset of symptoms <3 months

Chronic GN: GN with onset of symptoms >3 months

Secondary GN: possible, probable or definitive GN presumed to have resulted from an extra-renal systemic illness e.g. viral hepatitis, malaria, syphilis, etc.

Primary GN: possible, probable or definitive GN presumed to be of renal origin

Recurrent GN: history of previous possible, probable or definitive GN at any time before current presentation which has resolved spontaneously or with treatment

Rapidly progressive GN: possible, probable or definitive GN with acutely rising serum creatinine level or progressive oliguria (urine output <0.5 ml/kg/hour for 6-12 hours) over a period of days or weeks but not for more than 3 months

Crescentic GN: kidney biopsy evidence of glomerular crescents

Post-streptococcal GN (PsGN): possible, probable or definitive GN with either of the following

1. Evidence of recent streptococcal infection with rising titer of anti-streptococcal antibody
2. Spontaneous resolution of serum creatinine without treatment with immunosuppressive medication over a period of days or weeks but not more than 8 weeks

Lupus nephritis (LN):

Probable LN: possible, probable or definitive GN with either of the following

1. Previous diagnosis of systemic lupus erythematosus (SLE)
2. Positive serum anti-nuclear antibodies (ANA) and/or anti-double stranded antibodies (Anti-DS Abs)
3. Other multisystem features of lupus

Definitive LN: kidney biopsy evidence of LN

Response

complete remission, proteinuria < 0.3 g per 24 hours and normal serum creatinine

Partial remission proteinuria >0.3 but < 3.5 g per 24 hours or a decrease in proteinuria by at least 50% from the initial value and <3.5 g per 24 hours stable serum creatinine(change in creatinine < 25% or decrease <50% from baseline, and stable serum creatinine

Study Variables

Dependent variables

Outcome of glomerular disease, need for RRT

Independent variables

The independent variables are age, sex, and educational status,

Data processing and analysis

Each completed questionnaire will be entered in to Statistical Package for Social Sciences (SPSS) version 20 and then prepared for analysis. Continuous variables with normal distribution will be expressed as mean and standard deviation, and with non-normal distribution as median and interquartiles. Categorical variables will be expressed as proportions. Frequencies and cross tabulations will be used to summarize descriptive statistics and texts, tables and graphs will be used for data presentation. Proportions of categorical variables will be compared using Pearson chi-square test.

Ethical considerations

Ethical clearance will be obtained from St. Paul's Hospital Millennium Medical College Institutional Review Board (IRB). All the participants will be informed about the study, and written informed consent will be obtained from all who is agreed to participate before enrolment in the study. If participants are unable to provide written consent, they will be excluded from the study.

Dissemination of results

The findings of the study will be presented on the annual medical conference of SPHMMC and will be published on locally accessible journals.

Chapter 5 Results

Among 150 patients admitted to SPHMMC in medical ward from September 2009 –september 2010 glomerular disease defined by clinical means accounted for 33%(44) of the patients.

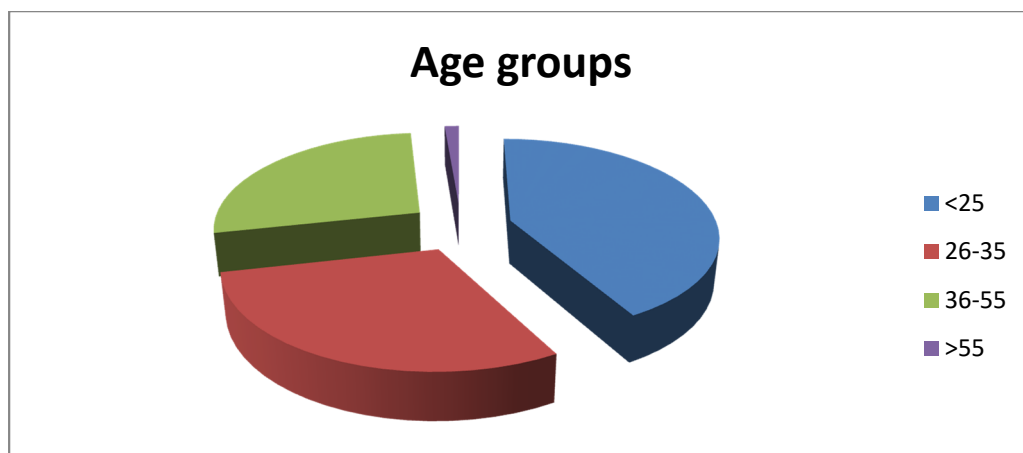
Sociodemographic characteristics

Men accounted for 24 (54.5%) of the study sample. The mean age was 33 (+/-14.9) years, with 35 (79.5%) of patients under the age of 45years and 17(38.6%) patients under 25 years. Most of the patients 38 (86.4%) came from Addis Ababa and Oromia.(table1)

Table 1

Socio demographic characteristic	Category	Frequency n(44)	Percent
Sex	Male	24	54.5%
	Female	20	45.5%
Age	<25	17	38.6%
	26-35	12	27.3%
	36-45	6	13.6%
	46-55	5	11.4%
	>55	4	9.1%
Region	Addis Ababa	19	43.2%
	Oromia	19	43.2%
	Amhara	2	4.5%
	SNNPR	2	4.5%
	others	2	4.5%
Marital status	Married	16	36.4%
	Never married	17	38.6%
	Divorced	1	2.3%

Figure 1



Clinical feature

The commonest presenting symptoms were body swelling 41(93.2%), hematuria 28(63.6%) and decreased in urine output 27(61.4%). All of the patients presented either with body swelling or hematuria 44(100%). The mean time of presentation is 3.2weeks (+/-2.9)

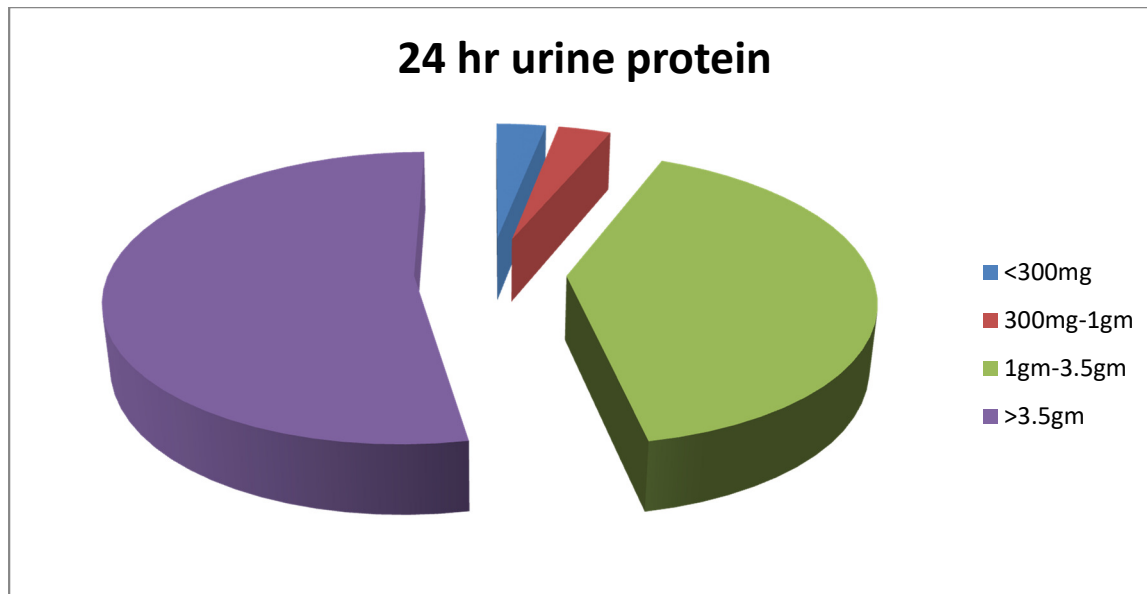
Table 2

	Specific symptoms	Frequency	Percent
Presenting symptoms	Body swelling	41	93.2%
	Hematuria	28	63.6%
	Decreased urine output	27	61.4%
	History of increased blood pressure	6	13.6%
	Nausea / vomiting	18	40.9%
	Sore throat/skin lesion	7	15.9%
	Joint pain/swelling	2	4.5%
	Others	2	4.5

Renal function test and urine analysis

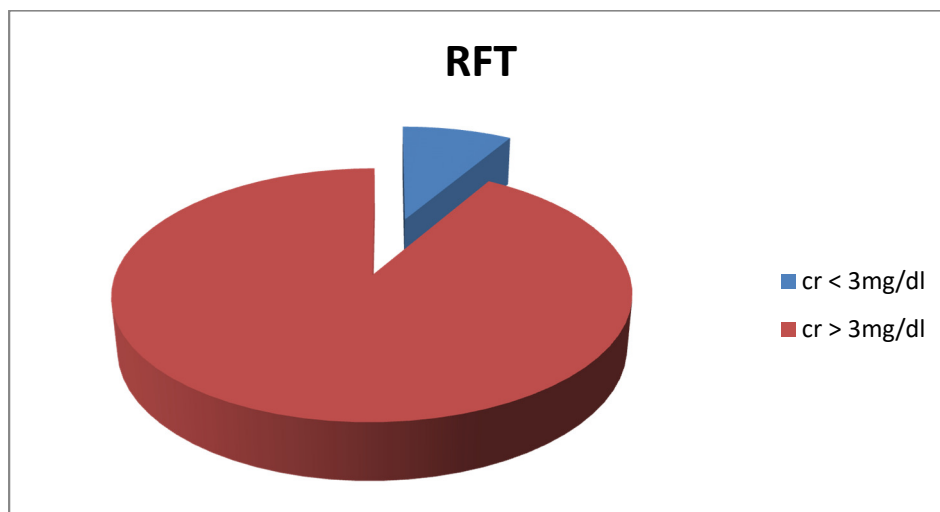
All of the patients have hematuria and proteinuria on dipstick examination. 93% has above 2+ proteinuria and 97% have above 2+ hematuria. Quantitative assessment of urine protein was done in 75% of patients and 93% have 1gm and above. At presentation 69.9% are hypertensive and 30.25 are normotensive and there were no hypotensive records. Among hypertensive 55% are stage 2 hypertensive.

Figure 2



The mean cr among the group is 6.3mg/dl (+/-5) and 68.2% presented above 3mg/dl.(figure 3) The mean urea is 150mg/dl (+/-77).most of the patients (90%) are hypoalbuminemia and 63.3% are dyslipidemic

Figure 3



Serologic profile

Serologic profile assessment done among the patients the commonest was ANA it was done in 72.7% of patients and positive in 13% of patients.(figure 4) Followed by ASO abs was seen in 29.5% of patients all were negative.(figure 4)Only 11.4% of patients ANCA was assessed and all were negative. Compliment

profile was available for 61.45 of patients and 15% either C3 or C4 was consumed and 33% both were consumed.(figure 5)

Figure 4

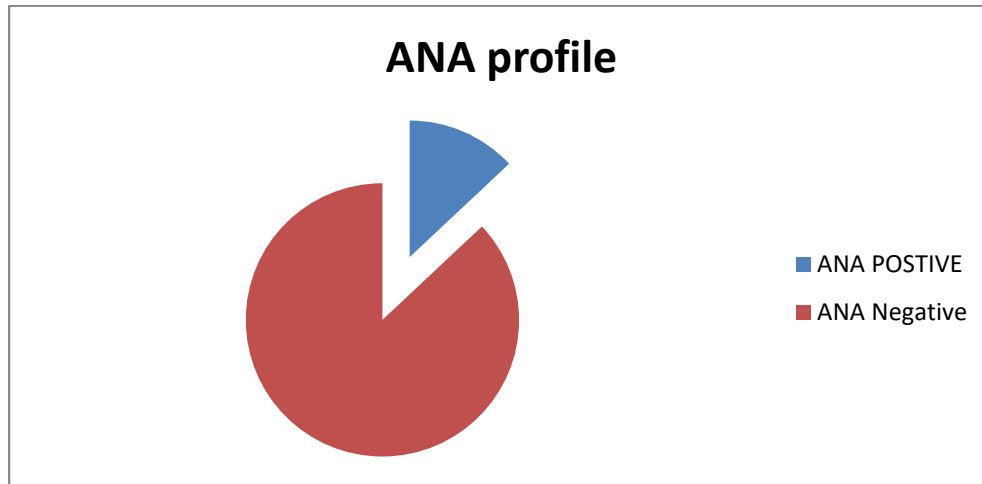
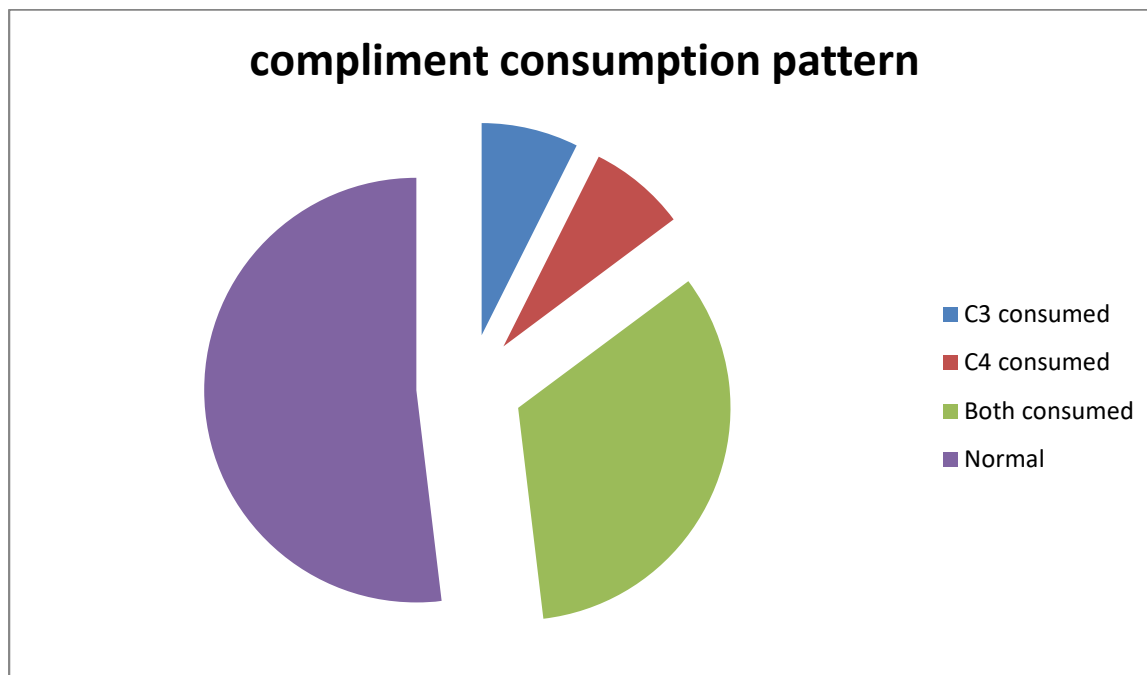


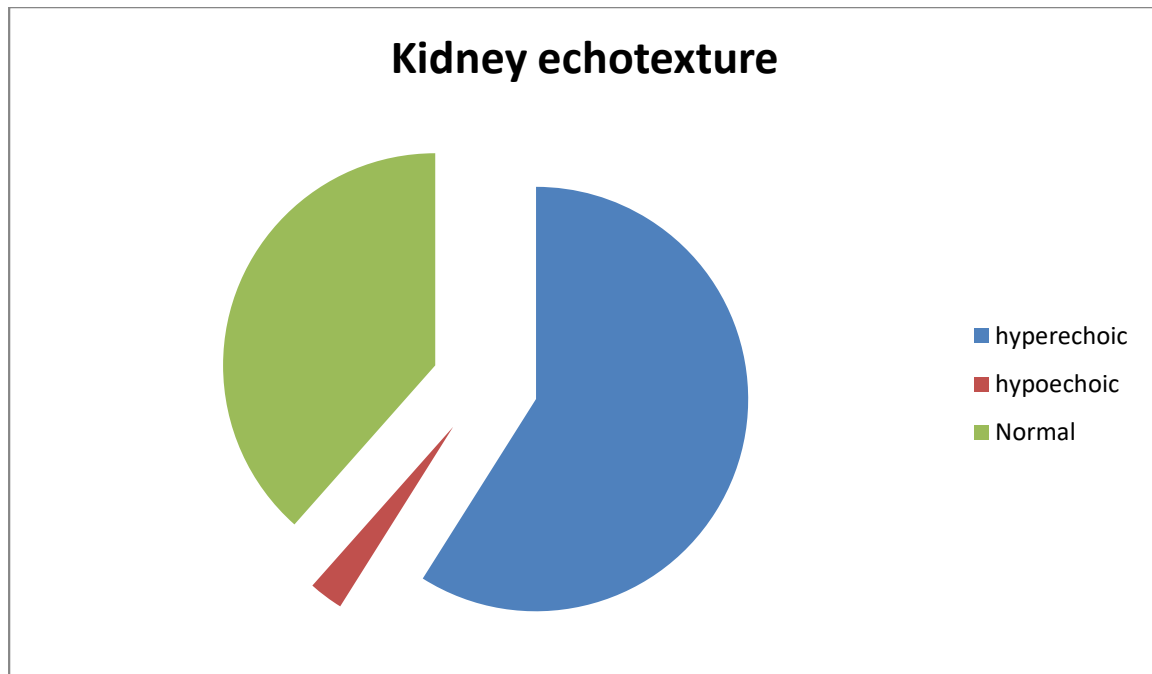
Figure 5



Imaging profile

Abdominal ultrasound was done in 97% of the patients.59%hyperechoic,38.5%normal and 2.6%hypoechoic.(figure6)kidney size was normal 95.35% and nephromegaly in 4.7%

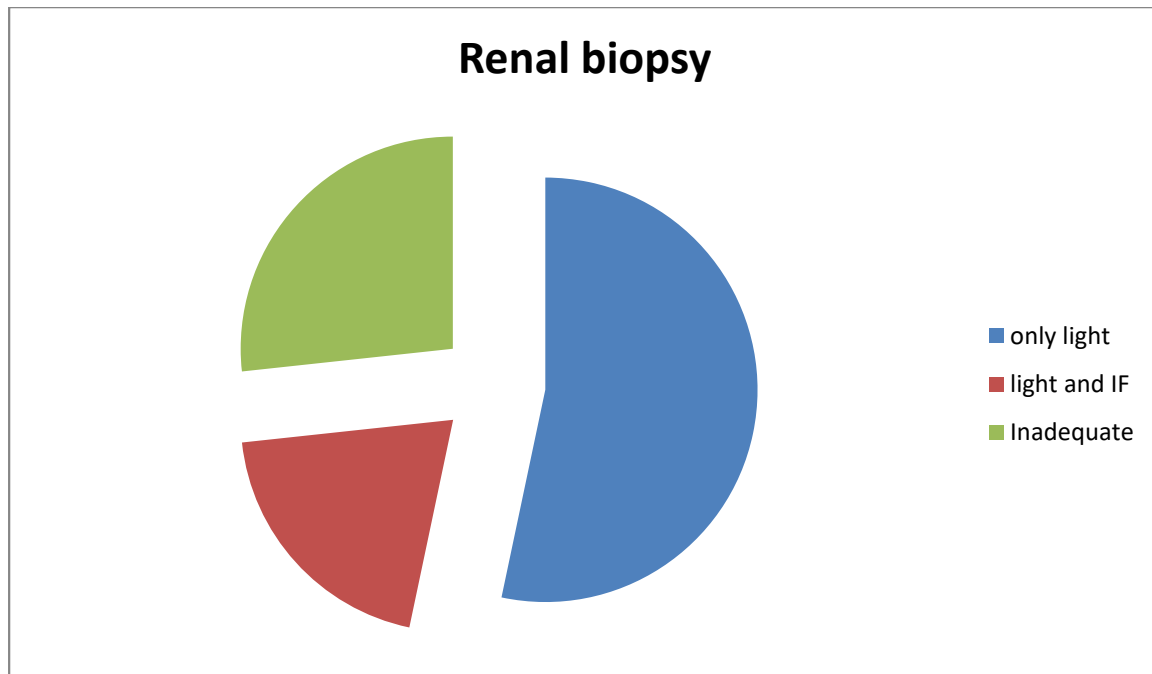
Figure 6



Renal biopsy

Renal biopsy was done in 34.1% and no biopsy was done in 65.9%.majority only light microscopy was done 53.3%,light and immunofluorescence was available in 20% and 26.7% biopsy sample was inadequate.(figure7)

Figure 7



Renal replacement treatment

The commonest renal replacement treatment was hemodialysis. 40.9% required hemodialysis and 59.1% did not require hemodialysis. (Figure 8) The commonest indication for hemodialysis was refractory fluid overload, followed by uremic complication, hyperkalemia and metabolic acidosis. (figure9)

Figure 8

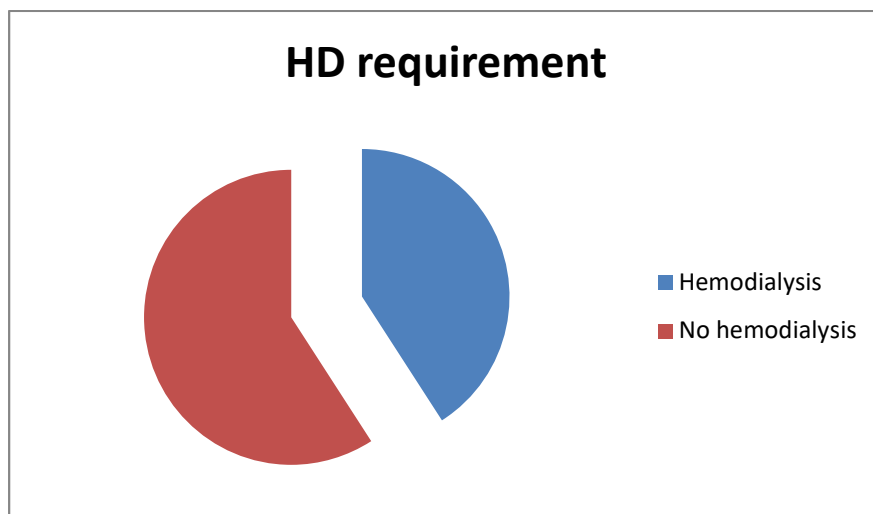
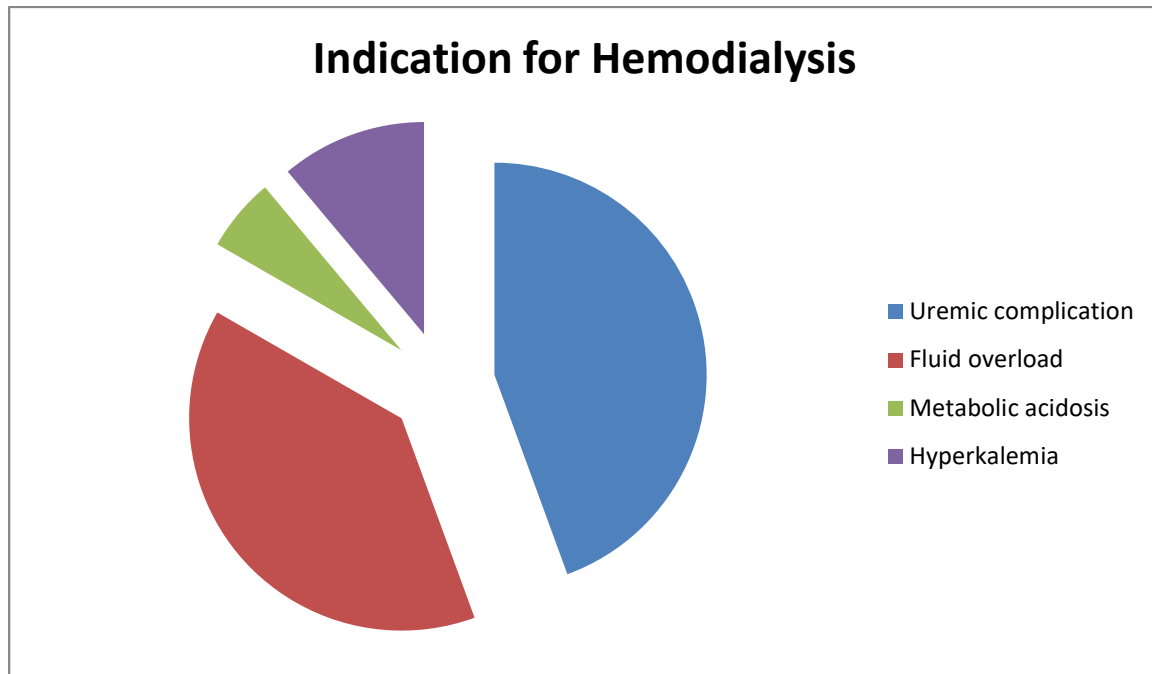


Figure 9



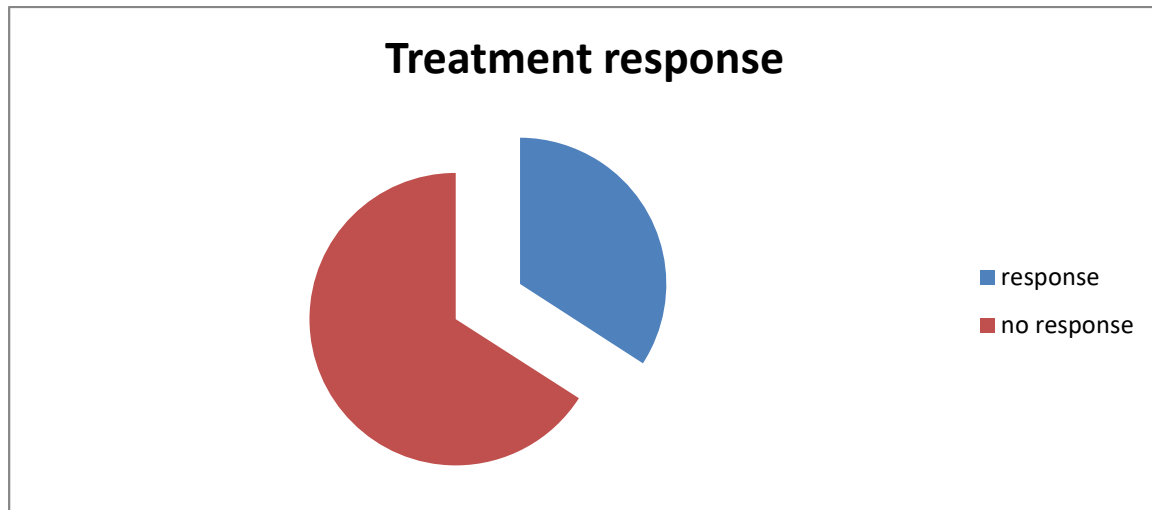
Treatment response

The majority of patients received antihypertensive and antiproteinureic agents and prednisolone. methylpredisolone used in 21.4%, cyclophosphamide 16.7% and MMF in 11.9%. (table 3). Treatment response was seen 58.5% which showed response in RFT complete or partial response and 37.5% remission in proteinuria. (figure 10)

Table 3

Medication	Frequency	Percent
Antihypertensive and antiproteinureic agents	33	76.2%
Prednisolone	31	73.8%
Cyclophosphamide	7	16.7%
MMF	5	11.9%
Methylprednisolone	9	21.4%

Figure 10



Chapter six Discussion

In our study glomerular disease account for 33% of admission with AKI. This is comparable with figures in Africa. Glomerular disease account for the commonest cause of CKD in Africa 22%.(14) timely undiagnosed and untreated glomerular disease will result in CKD This study revealed that glomerular disease affect young individuals in their economically productive years and thus contrasting with the advanced age of patients in developed countries.(6) Male outnumber females this consistent with other studies of primary glomerular disease.

Most of the patients presented with RIFLE F, $cr > 3mg/dl$ the patients also have symptoms of uremia like vomiting seen in 40% of our patients these is also seen in other studies owing late referral(15)

Serologic markers pertinent for the diagnosis of glomerular disease were done only in few patients thus delaying and hampering the diagnosis. Only 34% of patients have renal biopsy because of cost and lack of center handling the tissue in our country. These finding is also evident in other studies showing lowest biopsies performed in sub-Saharan Africa. (9)

Response to treatment complete and partial remission was seen in 60% of patients. These is difficult to compare with other studies because glomerular disease is heterogeneous disorder with different disease and biopsy in our study was low. Although different races have variable response to treatment African American with the lowest response to treatment.(16)

The strength of the study is the first study in our setup that tries to determine the magnitude of glomerular disease and determine gaps in diagnosis and treatment. We also tried to determine response to therapy. Limitation of the study due to cross sectional design follow up of patients wasn't available. Diagnosis of glomerular disease was based on biopsy in only 34% Of patients

Conclusion and Recommendation

Glomerular disease significant proportion of patients admitted with AKI. It affects young people. Diagnosis and work up is inadequate in most patients

we need to implement preventative strategies to standardize diagnosis and management of glomerular disease we should also design a prospective trial to better characterize pattern of glomerular disease .

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Appendix I

Questionnaire

- | | |
|------------------------------|--|
| 1. Sex | 1. Male
2. Female |
| 2. Age | ----- |
| 3. Ethnic group | 1. Amhara
2. Tigrean
3. Oromo
4. SNNPR
5. Others |
| 4. Educational status | 1. No formal schooling
2. Less than primary school
3. Primary school completed
4. Secondary school completed
5. High school completed
6. College/university completed
7. Post- graduate degree |
| 5. Occupation | ----- |
| 6. Marital status | 1. Never married

2. Currently married |

3. Separated
4. Divorced
5. Widowed
6. Co-habituating

GN related questions

1. Presenting symptom

1. Bloody urine
2. Hx of increased blood pressure
3. Foaming of urine
4. Body swelling
5. Decreased urine amount
6. Joint pain or swelling
7. Hx sore throat or skin lesion
8. Nausea or vomiting
9. Fast breathing or acidosis
10. Uremic encephalopathy
11. Uremic pericarditis

2. Childhood similar history

1. Yes
2. No

3. Previous Hx of urinary complaints or Rx

1. Yes
2. No

4. Any comorbidities

1. Yes
2. No

- 5. If yes,**
1. Hepatitis B
 2. Hepatitis C

5,drug intake

6. BP

1. Stage 1

2. Stage 2

3. Normal

4,hypotensive

Investigation modalities

1. Urine analysis

Dip stick hematuria

1. Yes

2. No

If yes

1+

2+

3+++

Proteinuria

1.yes

2.No

If yes

1+

 2_{++}

3+++

Microscopy

Dysmorphic RBCs or RBC Casts

1. Yes

2.No

2. Hemoglobin

1. >12 g/dl

2. 10-12 g/dl

3. $< 8\text{g/dl}$

3. calcium

1. Normal

2. high

3. low

4. phosphorous

1. Normal

2. high

3. low

5. 24 hour urine protein

1. <300mg
2. 300-10000gm
3. 1-2 gm.
4. 2-3.5gm
5. >3.5gm

6. Dyslipidemia

1. Yes
2. No

7. Albumin

1. Low
2. normal

Serology profile

- 1. ANA**
1. yes
 2. no

If yes,

1. positive
2. negative

- 2. ANCA**
1. Yes
 2. No

If yes,

1. Positive
2. negative

- 3. DsDNA**
1. yes
 2. no

If yes

1. positive
2. negative

4. ASO titer 1.yes
 2. no

If yes,

1. positive
2. negative

5. Compliment consumption profile

1. Yes

2. No

If yes,

1. C3 consumed
2. C4 consumed
3. Both consumed
4. Both normal

6. Was renal biopsy done

1. Yes

2.No

7, if yes

- 1,light microscopy
- 2,light & IF microscopy

8 If yes, findings suggest 1.MCD
2. IgA nephropathy

3. FSGS
4. MCGN
5. crescentic GN
6. others

Imaging profile

1. Renal size on ultrasound

1. Normal
2. Shrunken
3. nephromegaly

Treatment profile

1. Medication use

1. Prednisolone
2. Cyclophosphamide
3. Methylprednisolone
4. MMF

2. Response to therapy

1. Complete remission
2. Partial remission
3. No response
4. Death

3. Was RRT needed

1. yes

2. no

4. Indication for RRT

1. Refractory fluid overload

2. Uremic complication

4. Refractory hyperkalemia