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ORIGINAL ARTICLE

Predictive Value of Free Light Chain Ratio and Urinary M-Protein for Renal Involvement and Disease Progression in Multiple Myeloma

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ABSTRACT

Background: *Renal impairment is a frequent and serious complication of multiple myeloma (MM), often leading to poor prognosis. Serum free light chain (FLC) ratio and urinary M-protein are emerging biomarkers with potential predictive value for renal involvement and disease progression.* ***Aim of the study:*** *To evaluate the predictive value of serum FLC ratio and urinary M-protein levels for renal involvement and disease progression in patients with multiple myeloma.* ***Methods & Materials:*** *This prospective observational study was conducted at Bangabandhu Sheikh Mujib Medical University (BSMMU), Dhaka, from April 2023 to September 2024, including 54 MM patients. Clinical, biochemical, and renal parameters were analyzed. Statistical comparisons and multivariate logistic regression were performed to identify independent predictors of renal impairment.* ***Result:*** *Renal impairment was observed in 66.7% of patients. Mean serum FLC ratio and urinary M-protein were significantly higher in patients with renal dysfunction (p=0.002 and p=0.011, respectively). Both markers correlated positively with serum creatinine and β_2-microglobulin and inversely with eGFR. Multivariate analysis identified elevated FLC ratio (>10), urinary M-protein (>150 mg/24h), and β_2-microglobulin (>5 mg/L) as independent predictors of renal involvement.* ***Conclusion:*** *Elevated FLC ratio and urinary M-protein are strong, independent predictors of renal involvement and disease progression in multiple myeloma. Early assessment of these biomarkers can facilitate prompt intervention, preserve renal function, and improve prognosis.*

Keywords: *Multiple myeloma, Free light chain ratio, Urinary M-protein, Renal involvement, Disease progression, β_2-microglobulin*

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INTRODUCTION

The predictive value of the free light chain (FLC) ratio and urinary M-protein in multiple myeloma refers to their ability to forecast renal involvement and disease progression [1]. Globally in 2022, there were approximately 188,000 new cases, with an age-standardized incidence rate ranging from about 1.7 to 2.1 per 100,000 people [2]. In Bangladesh, Multiple myeloma accounts for about 10.5% of all hematological malignancies, which is comparable to global proportions [3]. The FLC ratio is a sensitive biomarker used to diagnose plasma cell disorders and assess disease burden; a high FLC ratio at diagnosis is strongly associated with early renal damage and a higher risk of disease progression, especially in light-chain multiple myeloma [4] . Urinary M-protein (also called monoclonal proteinuria) quantifies the amount of monoclonal protein excreted in urine, and elevated levels (≥200 mg/24h) in patients with a high FLC ratio (≥100) are linked to a significantly increased risk of progression to symptomatic multiple myeloma or AL amyloidosis, as well as a higher likelihood of renal failure [5]. Key risk factors for multiple myeloma include both genetic and lifestyle components. Several genetic variants, such as those in the DNAH11, ULK4, DTNB, and VDR genes, have been associated with increased risk, and there is strong evidence for a heritable component, especially in individuals with a family history of cancer or early-onset disease [6]. Obesity and excess body fat are well-established modifiable risk factors, with each 5 kg/m^2 increase in adult BMI linked to a 10% higher risk of developing multiple myeloma; higher waist circumference and predicted fat mass also contribute to increased risk [7]. Other factors that may increase risk include physical inactivity, diabetes, and higher socioeconomic status, which are associated with higher incidence rates globally [8]. Certain inflammatory markers, such as elevated levels of specific cytokines (e.g., monocyte-specific chemokine-3, vascular endothelial growth factor, interleukin-10, and interleukin-7), have also been linked to increased risk, while lower levels of tumor necrosis factor-beta are associated with higher risk [9]. There is some evidence that higher serum vitamin B6 and blood carnitine may increase risk, while higher omega-3 fatty

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acids and longer telomere length may reduce risk. However, these findings are less definitive [10] . Management and treatment of multiple myeloma have advanced significantly, with a focus on personalized approaches tailored to patient age, overall health, and risk stratification. For newly diagnosed patients eligible for transplant, the standard of care includes quadruplet regimens (often combining an anti-CD38 antibody, proteasome inhibitor, immunomodulatory drug, and dexamethasone), followed by autologous stem cell transplantation and maintenance therapy with lenalidomide to prolong remission [11]. Transplant-ineligible patients also benefit from anti-CD38-based combinations, and maintenance therapy is tailored to risk level and tolerability [12]. Ongoing research continues to expand the therapeutic arsenal, with emerging agents and precision medicine approaches offering hope for improved outcomes and quality of life [13]. This study aimed to evaluate the predictive value of the serum free light chain (FLC) ratio and urinary M-protein levels for assessing renal involvement and predicting disease progression in patients with multiple myeloma.

METHODS & MATERIALS

This prospective observational study was carried out in the Departments of Nephrology and Hematology at Bangabandhu Sheikh Mujib Medical University (BSMMU), Dhaka, over an 18-month period from April 2023 to September 2024. The study aimed to evaluate the predictive value of serum free light chain (FLC) ratio and urinary M-protein in assessing renal involvement and disease progression among patients with multiple myeloma (MM). A total of 54 patients diagnosed with multiple myeloma were enrolled through purposive sampling.

Inclusion Criteria:

- Adults aged ≥20 years of either sex.
- Confirmed diagnosis of multiple myeloma according to International Myeloma Working Group (IMWG, 2019) criteria.
- Evidence of renal involvement, defined as serum creatinine >2 mg/dL or urinary protein-to-creatinine ratio (uPCR) >300 mg/g.

Exclusion Criteria:

- Pre-existing chronic kidney disease (CKD) unrelated to multiple myeloma.
- Acute kidney injury secondary to infection, dehydration, or medication use not attributable to MM.
- History of malignancies other than multiple myeloma.
- Use of nephrotoxic drugs within the past 3 months prior to diagnosis.
- Severe hepatic impairment or chronic liver disease affecting protein metabolism.
- Patients on dialysis before MM diagnosis or without available baseline renal data.
- Pregnant or lactating women.

Ethical Considerations

The study protocol was reviewed and approved by the Institutional Review Board (IRB) of BSMMU. Written informed consent was obtained from all participants. Data confidentiality and patient anonymity were strictly maintained throughout the research process.

Data Collection

Demographic and clinical data including age, sex, BMI, comorbidities (hypertension, diabetes mellitus), and clinical features (presence of edema, anemia) were retrieved from hospital records. Radiological data regarding bone lesions were obtained from available imaging reports.

Laboratory Assessment

Baseline laboratory parameters were obtained at the time of diagnosis. Hemoglobin, serum creatinine, blood urea, calcium, and albumin were analyzed using standard automated biochemical analyzers. Serum β_2-microglobulin was measured using the VIDAS PC enzyme-linked fluorescent assay (ELFA) method.

Serum free light chain (FLC) κ and λ levels were quantified by immunonephelometry on a Beckman Coulter/Siemens platform, and the κ/λ ratio was calculated; values greater than 10 were considered elevated.

Twenty-four-hour urinary M-protein was determined by urine protein electrophoresis (UPEP), with values >150 mg/24h regarded as elevated. Serum albumin concentration was measured using the bromocresol green (BCG) method, and serum creatinine and blood urea were analyzed by the alkaline picrate (Jaffe) method. The estimated glomerular filtration rate (eGFR) was calculated using the Modification of Diet in Renal Disease (MDRD) equation.

Assessment of Renal Function

Renal function was evaluated by measuring serum creatinine and calculating the estimated glomerular filtration rate (eGFR) using the CKD-EPI equation. Patients were categorized as follows:

- Normal renal function: Cr <1.2 mg/dL
- Mild impairment: Cr 1.2–2.0 mg/dL
- Moderate impairment: Cr 2.1–4.0 mg/dL
- Severe impairment: Cr >4.0 mg/dL or on dialysis

Statistical Analysis

All statistical analyses were performed using SPSS version 26.0. Continuous variables were presented as mean ± standard deviation (SD) and compared between groups using the Student's t-test or one-way ANOVA, as appropriate. Categorical variables were summarized as frequency and percentage and analyzed using the Chi-square test. The Pearson's correlation coefficient was applied to assess the relationships. To determine independent predictors of renal involvement, multivariate logistic regression analysis was performed. A p-value of less than 0.05 was considered statistically significant in all analyses.

RESULT

Table I showed that most patients were aged 41–60 years (53.7%), with a mean age of 55.7 ± 11.8 years. Sex distribution was nearly equal (males 51.85%, females 48.15%). Most had normal BMI (72.22%), with a mean of 23.5 ± 1.79 kg/m^2. Hypertension (46.3%) was the most common comorbidity, followed by diabetes mellitus (20.37%). Edema was noted in 33.3% (mild) and 5.6% (moderate). Mild anemia was present in 72.22%, and moderate to severe in 22.22%. Bone lesions were detected in 62.96% of patients, while 37.04% showed none (Figure 1). The mean hemoglobin was 9.60 ± 2.10 g/dL, serum creatinine 2.12 ± 1.34 mg/dL, and blood urea 58.40 ± 29.60 mg/dL. Mean serum calcium and albumin were 10.40 ± 1.20 mg/dL and 3.20 ± 0.60 g/dL, respectively. Mean β2-

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microglobulin and FLC ratio were 5.92 ± 2.34 mg/L and 14.20 ± 21.30, while urinary M-protein excretion was 196.70 ± 142.30 mg/24h (Table II). Table III showed that 33.33% had normal renal function, while 66.67% had renal impairment—mild in 24.07%, moderate in 27.78%, and severe in 14.81%. The mean eGFR was 51.3 ± 18.9 mL/min. The impaired renal group had significantly higher FLC ratio (18.73 ± 24.54 vs 5.32 ± 7.11, p=0.002), urinary M-protein (230.40 ± 152.70 vs 121.60 ± 78.20 mg/24h, p=0.011), and β2-microglobulin (6.80 ± 3.60 vs 3.40 ± 1.70 mg/L, p=0.001). Serum creatinine was also higher (2.89 ± 1.42 vs 1.01 ± 0.22 mg/dL, p<0.001) (Table IV). Serum FLC ratio correlated positively with serum creatinine (r=0.48) and β2-microglobulin (r=0.56), and negatively with eGFR (r=−0.44). Urinary M-protein also showed positive correlations with serum creatinine (r=0.41) and β2-microglobulin (r=0.45), but negative with eGFR (r=−0.37) (Table V). Patients who showed disease progression had significantly higher serum FLC ratio (26.10 ± 31.40 vs 7.90 ± 10.50, p=0.004), urinary M-protein (254.80 ± 158.90 vs 162.30 ± 97.40 mg/24h, p=0.028), and β2-microglobulin (7.10 ± 3.90 vs 4.50 ± 2.20 mg/L, p=0.021). Their mean eGFR was notably lower (39.60 ± 16.80 vs 54.20 ± 19.10 mL/min, p=0.007) (Table VI). Table VII showed that elevated serum FLC ratio (>10) was a significant independent predictor (AOR: 3.84, 95% CI: 1.28–11.56, p=0.016), along with urinary M-protein (>150 mg/24h) (AOR: 2.93, 95% CI: 1.07–8.03, p=0.037) and β2-microglobulin (>5 mg/L) (AOR: 4.22, 95% CI: 1.38–12.86, p=0.012). Age >60 years was not significantly associated (p=0.47).

Table – I: Demographic characteristics of the study population (*n*=54)

Variable	Frequency (n)	Percentage (%)
Age group (years)		
20–40	7	12.96
41–60	29	53.70
>60	18	33.33
Mean ± SD	55.7 ± 11.8	
Sex		
Male	28	51.85
Female	26	48.15
BMI (kg/m^2)		
Normal (18.5–24.9)	39	72.22
Overweight (25–29.9)	15	27.78
Mean ± SD	23.5 ± 1.79	
Comorbidities		
Hypertension	25	46.30
Diabetes mellitus	11	20.37
Clinical signs		
Edema (+)	18	33.33
Edema (++)	3	5.56
Anemia status		
Mild (Hb 9–12 g/dL)	39	72.22
Moderate–severe (<9 g/dL)	12	22.22

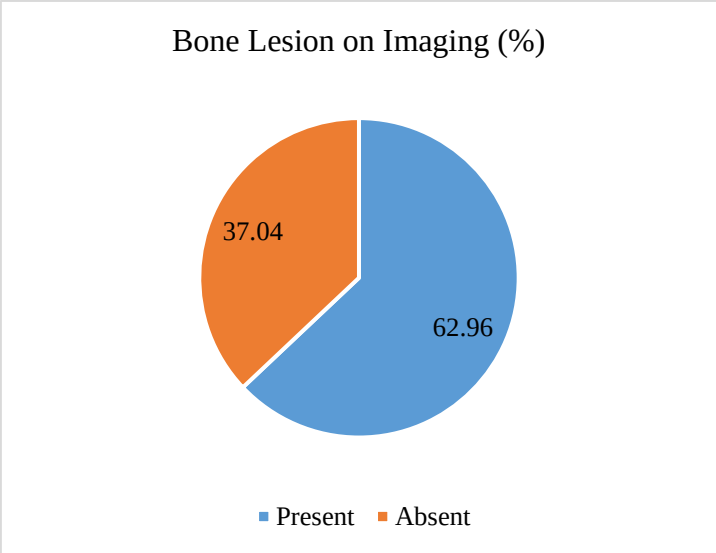

Figure – 1: Distribution of patients according to bone lesion on imaging (*n*=54)

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Table – II: Laboratory parameters of the study population

Parameter	Mean ± SD
Hemoglobin (g/dL)	9.60 ± 2.10
Serum Creatinine (mg/dL)	2.12 ± 1.34
Blood Urea (mg/dL)	58.40 ± 29.60
Serum Calcium (mg/dL)	10.40 ± 1.20
Serum Albumin (g/dL)	3.20 ± 0.60
β2-Microglobulin (mg/L)	5.92 ± 2.34
Serum Free Light Chain Ratio (κ/λ)	14.20 ± 21.30
Urinary M-Protein (mg/24h)	196.70 ± 142.30

Table – III: Distribution of renal involvement (*n*=54)

Category	Frequency (n)	Percentage (%)
Normal renal function	18	33.33
Mild renal impairment	13	24.07
Moderate impairment	15	27.78
Severe impairment	8	14.81
Mean eGFR (mL/min)	51.3 ± 18.9	

Table – IV: Comparison of free light chain ratio and urinary M-Protein between renal involvement Groups

Parameter	Normal (n=18)	Impaired (n=36)	P-value
Serum FLC Ratio (κ/λ)	5.32 ± 7.11	18.73 ± 24.54	0.002
Urinary M-Protein (mg/24h)	121.60 ± 78.20	230.40 ± 152.70	0.011
β2-Microglobulin (mg/L)	3.40 ± 1.70	6.80 ± 3.60	0.001
Serum Creatinine (mg/dL)	1.01 ± 0.22	2.89 ± 1.42	<0.001

Table – V: Correlation between FLC Ratio, urinary M-Protein, and renal function

Variable	Serum Creatinine (r)	eGFR (r)	β2-Microglobulin (r)
Serum FLC Ratio	0.48	−0.44	0.56
Urinary M-Protein	0.41	−0.37	0.45

Table – VI: Predictors of disease progression during follow-up

Parameter	Progressed (n=22)	Non-progressed (n=32)	P-value
Serum FLC Ratio (κ/λ)	26.10 ± 31.40	7.90 ± 10.50	0.004
Urinary M-Protein (mg/24h)	254.80 ± 158.90	162.30 ± 97.40	0.028
β2-Microglobulin (mg/L)	7.10 ± 3.90	4.50 ± 2.20	0.021
eGFR (mL/min)	39.60 ± 16.80	54.20 ± 19.10	0.007

Table – VII: Multivariate logistic regression for predictors of renal involvement

Variable	Adjusted OR (95% CI)	P-value
Serum FLC Ratio (>10)	3.84 (1.28–11.56)	0.016
Urinary M-Protein (>150 mg/24h)	2.93 (1.07–8.03)	0.037
β2-Microglobulin (>5 mg/L)	4.22 (1.38–12.86)	0.012
Age (>60 years)	1.45 (0.53–3.98)	0.47

DISCUSSION

Renal involvement is a common and serious complication in multiple myeloma, and identifying reliable biomarkers such as free light chain ratio and urinary M-protein is crucial for early prediction and monitoring of disease progression [14]. In this study, we evaluated the predictive value of serum free light chain (FLC) ratio and urinary M-protein for renal involvement and disease progression in multiple myeloma (MM). Our study comprised 54 patients with a mean age of 55.7 ± 11.8 years, predominantly aged 41–60 years (53.70%), and with a nearly equal sex distribution (male 51.85%, female 48.15%). These demographic characteristics align with epidemiologic trends reported in Bangladesh and globally, where MM incidence peaks in the fifth to sixth decade of life with a slight male predominance [3,15]. Regarding body composition, most patients had a normal BMI (72.22%), while 27.78% were overweight, reflecting the relatively balanced nutritional status in our study. Comorbidities were common, with hypertension observed in 46.30% and diabetes mellitus in 20.37% of patients, consistent with prior studies indicating that metabolic disorders frequently coexist in MM populations and may influence renal outcomes [16,17]. Clinically, edema was present in 38.89% of patients, and anemia was noted in 94.44% (mild in 72.22%, moderate–severe in 22.22%), reflecting the hematologic and renal manifestations typical of MM [18]. Bone lesions were observed in 62.96% of patients, highlighting the high skeletal morbidity due to osteolytic activity mediated by malignant plasma cells [19]. Laboratory evaluation demonstrated significant renal dysfunction, with a mean serum creatinine of 2.12 ± 1.34 mg/dL, mean blood urea of 58.40 ± 29.60 mg/dL, and mean eGFR of 51.3 ± 18.9 mL/min. Serum calcium, albumin, β2-microglobulin, serum FLC ratio, and urinary M-protein levels were also elevated in subsets of patients, reflecting both disease burden and organ involvement [20,21]. Renal impairment was present in 66.67% of patients, with moderate–severe involvement in 42.59%.

Patients with renal impairment had significantly higher serum FLC ratios (18.73 ± 24.54 vs 5.32 ± 7.11, p=0.002) and urinary M-protein levels (230.40 ± 152.70 vs 121.60 ± 78.20 mg/24h, p=0.011), as well as higher β2-microglobulin (6.80 ± 3.60 vs 3.40 ± 1.70 mg/L, p=0.001) and serum creatinine (2.89 ± 1.42 vs 1.01 ± 0.22 mg/dL, p<0.001). These findings corroborate earlier studies that demonstrated elevated FLC and urinary M-protein as key drivers of renal injury in MM, particularly in cast nephropathy [21,22]. Correlation analysis revealed positive associations between serum FLC ratio and serum creatinine (r=0.48) and β2-microglobulin (r=0.56), and negative correlation with eGFR (r=−0.44). Similarly, urinary M-protein correlated positively with serum creatinine (r=0.41) and β2-microglobulin (r=0.45), and negatively with eGFR (r=−0.37). These results highlight the pathophysiologic link between monoclonal protein burden and renal impairment, consistent with prior literature [14,22]. During follow-up, disease progression occurred in 40.74% of patients. Those who progressed had significantly higher baseline serum FLC ratios (26.10 ± 31.40 vs 7.90 ± 10.50, p=0.004), urinary M-protein levels (254.80 ± 158.90 vs 162.30 ± 97.40 mg/24h, p=0.028), and β2-microglobulin (7.10 ± 3.90 vs 4.50 ± 2.20 mg/L, p=0.021), and lower eGFR (39.60 ± 16.80 vs 54.20 ± 19.10 mL/min, p=0.007). These findings are in line with previous studies indicating that elevated FLC and M-protein levels at diagnosis are associated with aggressive disease and shorter progression-free survival [23]. Multivariate logistic regression demonstrated that serum FLC ratio >10 (OR 3.84, 95% CI 1.28–11.56, p=0.016), urinary M-protein >150 mg/24h (OR 2.93, 95% CI 1.07–8.03, p=0.037), and β2-microglobulin >5 mg/L (OR 4.22, 95% CI 1.38–12.86, p=0.012) were independent predictors of renal involvement. Age >60 years was not statistically significant (p=0.47), suggesting that biochemical burden rather than chronological age is the primary determinant of renal risk in MM. These results align with prior studies emphasizing the prognostic value of FLC and β2-microglobulin in MM-related renal disease [24,25].

Limitations of the study: This study had several limitations. The relatively small sample size and single-center design may limit the generalizability of the findings. Renal involvement was assessed primarily using serum creatinine and eGFR, without renal biopsy confirmation. Follow-up duration was limited, preventing long-term outcome evaluation. Additionally, treatment heterogeneity among patients could have influenced disease progression. Despite these constraints, the study provides valuable insights into the predictive role of FLC ratio and urinary M-protein in multiple myeloma–related renal dysfunction.

CONCLUSION

This study demonstrated that an elevated serum free light chain (FLC) ratio and high urinary M-protein levels are significant predictors of renal involvement and disease progression in multiple myeloma. Patients with FLC ratio >10 and urinary M-protein >150 mg/24h had markedly higher risks of renal impairment and progression to advanced disease. The strong correlations between these biomarkers and serum creatinine, β_2-microglobulin, and eGFR highlight their diagnostic and prognostic value. These findings emphasize the importance of early assessment of FLC ratio and urinary M-protein at diagnosis for risk stratification and timely intervention, which may help preserve renal function and improve overall patient outcomes in multiple myeloma.

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