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Survival of patients with multiple myeloma diagnosed at the national center of hematology in Baghdad

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Abstract:

Multiple myeloma (MM) is a monoclonal malignant proliferation of plasma cells derived from a single clone. Due to the variety of organ dysfunction caused by this malignant disease with no curative therapy, hence survival becomes a challenge for this group of patients. The aim of this study was to analyze the epidemiology and survival of patients with MM attended the out-patient clinic of the national center of hematology in Baghdad/Iraq. A retrospective study conducted at the national center of hematology, from September 2009 to November 2013 in which the medical records of 46 patients with MM have been reviewed. Survival analysis was estimated by the Kaplan-Meier and multivariate Cox regression analysis. The mean age was 63.4 years, and 54.2% of patients studied were female. The most common clinical manifestations were anemia (93.4%), bone pain (86.9%), and renal impairment (39.1%). In survival analysis, the only variable that achieved statistical significance was renal impairment ($p = 0.025$). For mortality, renal impairment ($p = 0.017$) and coagulation abnormalities ($p = 0.012$) were significant in the Cox regression. In conclusion the epidemiological profile showed a slight predominance in females. Anemia and bone pain were the most frequent complaints. Renal impairment and coagulation abnormalities were associated with mortality for patients with multiple myeloma.

Keywords: *Survival, Multiple Myeloma, national center of hematology.*

Introduction:

Multiple myeloma (MM) is a malignant proliferation of plasma cells derived from a single clone. The tumor, due to its abnormal products and the host response result in various organ dysfunctions and symptoms like bone pain or bone fractures, renal insufficiency , susceptibility to infections, anemia, hypercalcemia, and sometimes, coagulation abnormalities, neurological symptoms and vascular manifestations of hyperviscosity (1). It is important to emphasize that bone complications is the main feature of multiple myeloma, which is responsible for the increased mortality and morbidity (2).

The etiology of MM remains unknown. It was found that the frequency of myeloma increase in individuals exposed to irradiation, woodworking, Leather, pesticide and exposure to petroleum derivatives (1).

Several chromosomal abnormalities were found, with predominance of deletions 13q14, deletions 17p13 and abnormalities of 11q1. MM is the second most prevalent blood cancer after non-Hodgkin lymphoma, comprising 1% of all the cancers with an estimated 86,000 new cases of MM each year in the world (3, 4). There are estimated of 62,546 deaths per year of MM, approximately 2% of all cancer deaths (5). In the USA, the MM is more common among Afro-descendants and occurs more often in men than in women with ration of (3: 2) (3). The risk of developing MM increases with age (6), and being incurable disease, the average 5 years survival is 44.9 % and less than 10% of patients with MM live longer than 10 years(3,7,8,9).

The main clinical manifestation of myeloma is related to bone destruction (10,). This complication results from imbalance in bone formation and resorption (2). Bone pain is the most common symptoms of MM, the osteolytic lesions induce fractures of long bones or compression fractures of the vertebral spine (3). Another important comorbidity is increased susceptibility to infections, primarily attributable to immunodeficiency status characterized by reduced in production of immunoglobulins resulted from the underlying disease (11, 12). Besides, malignant cell growth occurs within the environment of Bone marrow result in crowding this place with neoplastic cells leading to weakening of the immune system and increasing the risk of infection(3). The

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renal insufficiency is present in approximately 20% of patients with MM. More than 50% of newly diagnosed patients have a decrease in creatinine clearance; and around 9% need dialysis for severe renal insufficiency (13,14). Several studies reported that during the course of MM, 15% to 30% of patients may have manifestations of bleeding tendency, which vary according to the type (15% IgG and 30% IgA) (15).

The treatment of MM has been changed dramatically with the introduction of anti-angiogenic therapy and proteasome inhibitors which consequently improved survival. All patients should be thoroughly evaluated and categorized in well-defined groups according to staging systems. Choosing suitable treatment for MM depends on the patient's clinical condition and stage of disease to which it is considered and then treatment decision is made (16-19). In asymptomatic patients with stage I, the recommendation is observation until its progression with symptoms and lesions in organ arise (19). Already ineligible patients for bone marrow transplantation (BMT), elderly or poor performance, the current recommendation is the use of combination from melphalan, prednisone, and thalidomide with doses adjustment. Some studies put some criteria for the adjusted use of proteasome inhibitor (bortezomib) in those patients (20).

For patients with myeloma eligible for BMT, with less than 60 years old and good performance, the Initial treatment should include thalidomide, dexamethasone and the use of bortezomib. Therapeutic options in patients with aggressive disease and unfavorable cytogenetic abnormalities (deletion of chromosome 13q) there is no consensus in the literature, but the options are restricted to the use of bortezomib associated with dexamethasone or using Vincristine, Adriamycin, Dexamethasone(VAD) protocol followed by BMT. For post-transplantation maintenance, one may be considered the use of zolindrenic acid and thalidomide ;while in patients with post-transplant relapse , there are multiple options can always be used for example considering the use of lenalidomide, dexamethasone, bortezomib or a second transplant for eligible patient (17-19).

The aim of this study was to analyze the epidemiological profile and factors associated with survival of patients Multiple myeloma.

Materials and Methods:

A retrospective cohort study conducted at the national center of hematology in Baghdad. Forty-six patients diagnosed with MM from September 2009 to November 2013 were enrolled. Data collected from reviewing the records of patients seen at the out-patients clinic and / or who were hospitalized at the national center of hematology ward. The data include the following variables (gender, age, education, address, bone pain, anemia, infection, renal impairment, bleeding or thrombosis, number of hospitalizations, type of treatment). The diagnosis of MM was done by bone marrow aspirate and biopsy with serum protein electrophoresis, other relevant investigation carried out for all patients include complete blood picture and blood film ,erythrocyte sedimentation rate, serum calcium, blood urea, serum creatinine, skeletal survey to detect lytic lesions and urine for Bence-Jones protein , Beta2 microglobulin, C-reactive protein, and lactate dehydrogenase . Measurement of free monoclonal light chains done for patients if available The paraproteins were measured using architect c 3000 USA fully automated (the measurement is done by immunoturbidometric method and the normal reference range was; IgG 5.4-18.2 g/l, IgA 0.63- 4.84 g/l, IgM 0.22- 2.93 g/l, IgE <200). All the patients were designated based on diagnostic criteria of IMWG(20) .

I. Asymptomatic myeloma (smouldering myeloma).
M-protein in serum more or equal to 30 g/l and/or
Bone marrow clonal plasma cells more or equal of 10%
No related organ or tissue impairment (no end organ damage, including bone lesions) or symptoms
2. Symptomatic multiple myeloma.
M-protein in serum and/or urine
Bone marrow (clonal) plasma cells* or plasmacytoma
Related organ or tissue impairment (end organ damage, including bone lesions)

All patients were staged according to Durie and Salmon staging system (21).

Treatment protocol was chosen according to patients clinical evaluation and performance status, these protocols included melphalan plus prednisolone, thalidomide plus dexamethasone, vincristine plus Adriamycin plus dexamethasone (VAD) or bortezomib (velcade) containing regimen which either velcade, thalidomide, dexamethasone (VTD) , velcade, melphalan , prednisolone (VMP) or velcade, cyclophosphamide, dexamethasone (VCD).

Statistical analysis:

Data were analyzed using SPSS version 18. The independent variables were assessed by bivariate analysis using Chi-square test. Survival analysis was estimated by the Kaplan-Meier method using the log-rank for comparison of each exposure. Multivariate analysis controlling for factors associated with mortality was performed using Cox regression test .Confidence level was 95%. The cutoffs of the independent variables were based on conceptual models. Differences were considered as statistically significant at $P<0.05$.

Results:

The total number of patients with MM in this study was 46 patients. The pre-treatment clinical characteristics are shown in Table 1. MM was slightly more in females (54.2%), mean age was 63.4 ± 9.93 years with range (36 to 83 years). Table 2 shows the main features of laboratory aspects of MM. Importantly, 43 patients were complained of anemia (93.4%), bone pain occurred in(86.9%). most of patients had a degree of bone involvement with osteoporosis and / or osteolytic lesions. Of the 46 patients evaluated, 39.1% of patients had or developed renal impairment during the course of disease. Serum calcium was altered (hypo or hypercalcemia) in 35 % of patients. Coagulation abnormalities were detected in 10.8%

and 4.3% had venous thrombosis. Neurological symptoms occurred in 15 of the 46 patients analyzed, corresponding to 32.6% (Table 2).

Patients with multiple myeloma survived an average of 35.43 ± 29.41 months ranging between 2 months and 51 months from diagnosis. There were 13 deaths (28.2%).

When comparing the survival time by Kaplan-Meier analysis, the only variable that showed statistical significance was renal impairment (p = 0.025), in which the median survival of those who developed renal impairment was 11.26 months (95% CI = 9.45 to 23.08) as shown in table 3 and (fig. 1). It was evidenced also that patients with clotting abnormalities had low survival rate (mean 21.42 months, 95% CI = 11.24 to 38.59), but this was statistically insignificant (p = 0.715) as shown in table 3.

Multivariate analysis using the Cox regression test for independent variables associated with mortality rates showed patients with significant renal impairment (HR = 4.46, 95% CI: 1.29 to 15.42, p = 0.018) and coagulation abnormalities (HR = 12.61, 95% CI: 1.79 to 88.91, p = 0.011) had increased risk of death, with a statistically significant association (Table 4).

Table 1: pre-treatment clinical characteristics of patients with MM

Variables		Number	percent
Sex	Males Female	22 24	45.8 54.2
Age (years) *		63.4 ± 9.93	Range (36-83)
bone pain	yes no	40 6	86.9 13.1
fractures	yes no	10 36	21.7 78.3
renal impairment	yes no	18 28	39.1 60.9
anemia	yes no	43 3	93.4 6.6
Coagulation abn.	yes no	5 41	10.8 89.2
neurological features	yes no	13 33	28.2 71.8
venous thrombosis	yes no	2 44	4.3 95.7

*Values are expressed as mean ± SD

Table 2: summary of laboratory characteristics of patients with MM

variables	Mean± SD	Range
Hb g/dl	9.3±2.4	6.7-13.8
ESR mm/hr	107±41.2	23-142
WBC count $X10^9$/ L	7.13±6.1	4.5-13.4
Platelets count $X10^9$/L	237±92	120-470
Blood urea mg/dl	67.4±34.1	25-230
S. creatinine mg/dl	1.86±1.2	0.6-4.4
S. Ca mg/dl	9.8±1.7	8.4-13.5
Total s.protein g/dl	7.5±1.8	5.4-13.4
S. Albumine g/dl	3.33±0.46	2.3-4.3
S. Globuline g/dl	5.44±1.87	3.4-11.3
Bone marrow blasts %	43±21.3	18-85

Table 3: Comparison of survival time by Kaplan-Meier analysis

Variables		Mean(months)	95%	P value
Sex	Males Female	24.36 39.44	15.83 to 36.82 22.74 to 42.95	0,511
Renal impairment	yes no	11.26 41.86	9.45 to 23.08 23.94 to 50.79	0,025 *
Anemia		Censored	Censored	0,634
Serum calcium	Normal Increased	32.49 26.85	22.74 to 44.92 14.39 to 37.42	0,332
Coagulation abnorm.	yes no	21.42 31.51	11.24 to 38.59 23.61 to 39.72	0,715
neurological features	yes no	24.53 31.35	15.98 to 32.28 21.87 to 38.93	0,857
venous thrombosis	yes no	25.63 33.87	15.16 to 37.40 23.05 to 39.89	0,634
Bone pain	yes no	25.89 33.15	21.56 to 44.10 000 to 49.57	0,413

* Statistically significant

Table 4: Multivariate analysis of independent factors associated with death

Variables	RR (crude)*	HR (adjusted)#	95% CI$	p
Sex	0.97	2.06	0.68 to 6.55	0,211
Fractures	1.51	1.45	0.42 to 5.15	0,586
renal impairment	2.27	4.45	1.28 to 15.41	0,016 +
Anemia	0.0	1.06	0.0 -..x	0.992
Hypercalcemia	0.72	0.91	0.25 to 3.24	0,889
Coagulation abnormalities	1.17	12.59	1.89 to 88.81	0,012 +
neurological symptoms	1.12	0.57	0.15 to 2.39	0.456
Thrombosis	0.92	2.72	0.46 to 16.44	0,264
MP	0.61	0.40	0.11 to 1.31	0,126
VTD	0.83	8.16	0.52 to 57.14	0,123
VAD	0.0	0.0	0.0 - ..x	0,971
Thal-Dex	0.0	0.0	0.0 - ..x	0,946

* RR - crude relative risk; # HR - hazard ratio, adjusted by Cox regression; $ 95% CI: confidence interval of 95%; + Statistical significance; MP= melphalan plus prednisolone; VTD= velcade, thalidomide, dexamethasone ;VAD= vincristine plus adriymycin plus dexamethasone ; Thal-Dex= thalidomide plus dexamethasone.

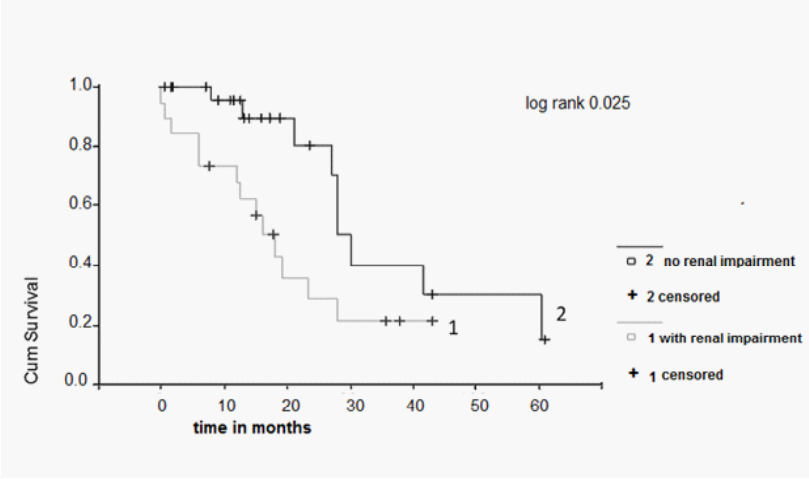

Fig. 1: Kaplan-Meier survival curve for multiple myeloma patients with or without renal impairment

Discussion:

This study showed that there was a slight female predominance (54.2%), which is similar to study done by Palambo et al (19), while other studies and supporting data from the literature including previous Iraqi study point to slight male predominance , this can be explained by the sample size or characteristics of population in area involved in this study.(3,9,25)

The average age of the patients was found to be 63.4 ± 9.93 years which is similar to study conducted by laubach et al(22) and another study in Brazil, with an average of 60.5 years(23).

The bone pain was observed in 40 patients (86.9%), and 21.7% had fractures, this was slightly lower than that reported by Roodman et al, who observed 70% of patients reported bone pain, differing only in 15% who had pathological fractures. it can be noticed that the main clinical features were related to bone disorder; as a consequence, patients in this study had late diagnosis(24).

Of the total examined patients, 39.1% presented or developed renal impairment during the course of the disease, a bit higher when compared to similar study conducted in Iraq (27%) (25) and lower than study done by Knudsen et al.(45%) (14).

Another common clinical manifestation found was anemia, with a prevalence of 93.4%. Other studies have also concluded that anemia was one of the most common complications in MM but with lower incidence to that of the present study (50% to 80%) (9,26,27). the main reasons for anemia predominance is the late presentation to specialized hematology clinics since most patients only sought medical attention after they developed backache, bone pain or other relevant symptoms and were referred to hematology from orthopedics clinics.

Concerning abnormalities in coagulation and venous thrombosis, which is major complication of hyperviscosity of myeloma; this study showed that the incidence of these complications is 10.8% and 4.3% for coagulation abnormalities and venous thrombosis respectively, this result is in contrast to other studies that showed higher frequency of 15% to 30% for disorders of hemostasis and 10% for venous thrombosis. These data are important since these neoplasms, especially MM, form a distinct group as a risk factor for the development of these disorders. As usually observed in other cancer settings, the malignant clone makes a cytokine environment liable for a hypercoagulable state. The increase of blood viscosity and impairment of platelet and coagulation function due to circulating monoclonal proteins are considered key mechanisms in the hemostatic abnormalities frequently detected in patients with MM .(16,28).

In the present study, the high frequency of renal impairment was an important data showing a decline in median survival of 11.26 months in patients with MM ($p = 0.025$), which is consistent with the findings in the literature. Conte et al, in his study divided the patients into two groups according to mortality: those who died less than six months, 52.5% developed renal impairment and those who died after 6 months of disease, the prevalence of renal impairment was 29% ($p = 0.006$)(9). Also Goldsmith et al found that early mortality related to renal impairment with incidence of 30%(13).
Regarding the multivariate analysis using Cox regression, the two variables that showed increased risk for death, independently, were renal impairment and coagulation abnormalities which were statistically significantly (HR = 4.45, $p = 0.016$ and HR = 12.59, $p = 0.012$ respectively).

In literature, different variable found in other studies have related to the higher risk of death. In a study done by Augustson et al where several factors had showed to influence the survival, including renal impairment, and infection in addition to beta-2 microglobulin and performance status. In the same study the coagulation abnormality was not included in a group of factors affecting survival.(29)

Another recent study done by Moreau et al where different variable were identified to be risk for death in MM including lactate dehydrogenase ,International Staging System 3

(ISS3), and adverse cytogenetic [t(4;14) and/or del(17p)(30). As for some limitations found in this study, it is possible to cite the lack / difficulty in clinical staging, the retrospective analysis of data, some incomplete information and the sample size.

In conclusion, the present study recognized the epidemiological profile for patients with multiple myeloma which is slightly more common in women, and usually presented in older age. The main factors associated with survival were the development of renal impairment and coagulation disorders.

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بقاء المرضى الذين يعانون من ورم نقي العظم المتعدد التي تم تشخيصها في المركز الوطني لأمراض الدم في بغداد

علاء فاضل علوان

المركز الوطني لأمراض الدم / الجامعة المستنصرية

الخلاصة:

ورم نقي العظم المتعدد هو تكاثر للخلايا الخبيثة وحيدة النسيلة من خلايا البلازما المستمدة من استنساخ واحد. يسبب هذا المرض خلل في كثير من وظائف الاعضاء الحيوية للجسم ويرجع ذلك إلى مجموعة متنوعة من ضعف جهاز المناعة الناجمة عن هذا المرض الخبيث ويصبح بالتالي بقاء المريض تحديا لهذه الفئة من المرضى. وكان الهدف من هذه الدراسة هو تحليل وبائيات وبقاء المرضى الذين يعانون من ورم نقي العظم المتعدد الذين يراجعون العيادة الخارجية للمركز الوطني لأمراض الدم في بغداد / العراق. دراسة استعادية أجريت في المركز الوطني لأمراض الدم، في الفترة من سبتمبر 2009 إلى نوفمبر 2013 حيث تم استعراض السجلات الطبيةل 46 مريضا 46 مصاب بورم نقي العظم المتعدد وتم تحليل البقاء من قبل كابلان ماير والتحليل متعدد المتغيرات كوكس والانحدار. كان متوسط العمر 63.4 عاما، وكانت 54.2٪ من المرضى الخاضعين للدراسة من الإناث. كانت المظاهر السريرية الأكثر شيوعا فقر الدم (93.4٪)، وآلام العظام (86.9٪)، والقصور الكلوي (39.1٪). في تحليل البقاء على قيد الحياة، كان المتغير الوحيد التي حققت دلالة إحصائية القصور الكلوي (p= 0.025). لفيات، كان القصور الكلوي 0.017 =(p) وشذوذ تخثر (p= 0.012) كبير في الانحدار كوكس. في الختام أظهر الوبائية غلبة طفيفة في الإناث. كان فقر الدم وآلام العظام الشكاوى الأكثر شيوعا. ارتبطت ضعف الكلى وشذوذ تخثر مع فيات لمرضى

كلمات البحث: البقاء على قيد الحياة، ورم نقي العظم المتعدد ، المركز الوطني لأمراض الدم.