ORIGINAL ARTICLE

# OUTCOME OF ALLOGENEIC BONE MARROW TRANSPLANT FOR IRAQI PATIENTS WITH ACUTE MYELOID LEUKEMIA

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## ABSTRACT

**The aim:** To assess the outcome of allogeneic transplant regarding the overall Survival (OS) and main predictors can effect the survival of such patients.

**Materials and methods:** The records of seventy-nine Iraqi patients diagnosed with non-promyelocytic AML, who underwent allogeneic bone marrow transplantation outside of Iraq between 2012 and 2019, had been reviewed. The information had been collected from the data available in Bone Marrow Transplant Centre in Baghdad Medical City. Overall survival had been calculated by Kaplan-Meier Method. Patients included in the study are those who were diagnosed with acute myeloid leukemia according to French American British classes with the exclusion of acute promyelocytic leukemia (M3), who were allotransplanted for being diagnosed with high risk cytogenetic, refractory to chemotherapeutic regimen, relapsed after achieving complete remission, secondary to transformation from other myeloid malignancies or remaining with positive measurable residual disease after treatment.

**Results:** The overall survival for 1 year, 2 years and 3 years were 63.20%, 55.09% and 46.58% respectively. The pre-transplanted factors found, no significant difference in overall survival regarding age, gender, extra medullary involvement. The transplant related criteria like stem cell source, presence of infection and type of conditioning regimen and incidence of any post-transplant complications do not predict overall survival apart from chronic graft versus host disease. Chronic GVHD were found to be significantly affecting overall survival.

**Conclusions:** The most common cause of death was disease relapse. Iraqi AML patients who were treated with allogeneic bone marrow transplant had shown to have encouraging overall survival.

**KEY WORDS:** Allogeneic bone marrow transplant, acute myeloid leukemia, Iraq

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## INTRODUCTION

Acute myeloid leukemia (AML) is an aggressive and progressive form of cancer that affects myeloid type of white blood cells [1]. The diagnostics of AML patients has been improved, particularly for those younger than 60 years old. About one third of such patients achieves long term cure and 70-80% ofthem reach complete remission with relapse risk for those with favorable cytogenetic abnormalities 29-42% , with intermediate risk in 39-60% and with high risk in 68-90%. For those older than 60 years old, the situation is worse and less than 10% of those older than 70 years reach long term remission and only 50-60% achieve complete remission (CR) with relapse rate of 80-90% [2,3] . Once remission achieved, further treatment is required to prevent relapse. This is termed as a consolidation phase, which is carried out by either chemotherapy or allo-HSCT. The choice depends on the patient`s age, the balance between risk of relapse and transplant related mortality and initial cytogenetic risk with chemotherapy, used for favorable risk group. Transplantation is done in such patients is considered to be of a high risk and an intermediate risk, with decision individualized [4]. Treatment with chemotherapy alone is unlikely to result in long term remission. Approximately half of younger patients and a large majority (more than 85%) of older patients with AML either do not achieve a CR (i.e., primary refractory) or relapse [5]. Patient who relapsed more than 12 months after initial chemotherapy can be given the same treatment again. For refractory AML cases, chemo radiation followed by allo-HSCT is considered the best option [6] which can induce long term survival in about 25% of treated.

## THE AIM

To assess the outcome of allogeneic transplant regarding the overall Survival (OS) and main predictors can effect the survival of such patients.

## MATERIALS AND METHODS

A cross sectional study included the medical record data of 79 patients, who were diagnosed with AML and underwent

allogenic hematopoietic stem cell transplant abroad of Iraq in different centers between 11th of December 2012 and 6th of November 2019. The information was collected from transplantation Centre in Baghdad medical city after taking verbal consent from the patients included in this study. Fisher equation was used to determine the sample size.

All patients diagnosed with non-promyelocytic AML, who were allotransplanted for either being relapsed, refractory to chemotherapeutic agents, had positive minimal residual diseases (MRD) after treatment or had a high cytogenetic risk stratification were included in this study.

Relapse cases are defined as those who had developed recurrence of the disease after achieving complete remission following first induction (CR1).

Complete remission was defined as a bone marrow blast cells percent of less than 5 % in a cellular marrow durable for at least 28 days with peripheral neutrophil count of 1.5* 109/L and platelet count above 100*109/L and absence of extra medullary disease before transplantation.

Patients who failed to fulfill the criteria of complete remission were considered to be in a non-remission state before transplant.

Refractory cases were defined as those who fail to achieve a complete remission after one or two cycles of induction with chemotherapy or those who achieve less than 50% reduction in blast numbers with more than 15% residual blast after one cycle of induction chemotherapy. Most allotransplanted patients were in the second complete remission (CR2) (76 patients), with remaining 3 patients in first complete remission (CR1), who were transplanted for having poor cytogenetic risk group.

High risk cytogenetic stratification was defined according to ELN risk stratification criteria [5]. Induction 3&7 protocol involving the use of anthracycline for three days and cytarabine arabinoside for seven days, was used as first induction regimen for those older than 14 years and medical research council (MRC) AML 15 protocol was used for younger patients.

On the other hand; FLAG – ida , CLAG , HiDAC and MiDAC protocols were also used for patients who either have failed first induction or relapsed after achieving CR1. Conditioning regimen used were myeloablative involving either total body irradiation (TBI) or fludarabine and busulfan or non-myeloablative regimen in whom the reports did not mention the type of chemotherapeutic agents used. With regard to HLA typing, PCR analysis for HLA-A , B and DRB was done. The stem cell source used was peripheral blood stem cells or bone marrow (with no mentioned reasons in enrolled reports). Acute and chronic GVHD were defined according to clinical manifestations as well as their occurrence prior to and after 100 days post-transplant. Overall survival was defined as the time length from date of transplantation till death or the end of the study.

Male patients made 59.49% of studied participants, while female patients made 40.51%, with male-to-female ratio of 1:1.

Age of participants at time of transplant ranged from 3-57 years, with a mean age ± SD of (29.14 ± 13.83) years and a median of 28 years. No significant difference in age was observed between males (27.74 ± 13.19) and females (31.59 ± 14.59), P-value = 0.677 (table I). Demographic and clinical characteristics of the transplant patients is provided in Table II. Most allotransplanted patients were in the second complete remission (CR2) (76 patients, 96.2%), with remaining 3, 3.7% patients in first complete remission CR1, who were transplanted for having positive minimal residual diseases (MRD) post consolidation or poor cytogenetic.

## STATISTICAL ANALYSIS

Statistical Package for Social Sciences (SPSS®) Software (version 23.0 for Linux®) was used to perform the statistical analysis for this study. Qualitative data are represented as numbers and percentages, while continuous numerical data are represented as mean ± standard deviation. Numerical variables were compared between study groups using Student's t-test, while categorical variables were compared using Chi-square test. Survival probability was estimated using Kaplan-Meier method. Data were represented using appropriate tables and visualized using appropriate figures. P value < 0.05 was considered statistically significant.

## RESULTS

Table III demonstrates pre-transplant and transplant patients characteristics, conditioning regimen used: myeloablative, involving either total body irradiation or fludarabine and busulfan in 56 (70.88%) patients and non-myeloablative regimen in 6 (7.59%) patients. The cause of using nonmyeloablative conditioning was mentioned in three patients; one due to underlying pulmonary fungal infection, one for being HCV-positive with liver disease and the third was shifted on the first day of myeloablative conditioning after being confused for more than 1 hour after cyclophosphamide infusion. The cause of the remaining three patients who received non myeloablative conditioning was also not mentioned in the reports. Also, no data regarding conditioning regimen was available in the records for 17 (21.5%) participants.

With regard to HLA typing, 72 (91.1%) patients were fully compatible with their donors; 2 (2.5%) had no available data in the records and 5 (6.3%) were not fully compatible (5/6 , 6/7 , 7/8, 75% and 50% compatibility as mentioned in their records). The stem cell source used was peripheral blood stem cells in 67 patients, bone marrow in 9 patients for non-mentioned reasons and three participants had no data available in their records. The commonest cause of death among patients who died was relapse in 51.35%, followed by sepsis in 29.73%, as detailed in Table IV.

Regarding overall survival, a total of 37 (46.8%) patients died, while 42 (53.1%) patients survived. Kaplan-Meier method was used to estimate survival probability. Overall survival rates of 1-year, 2-years, and 3-years were (63.20%), (55.09%), and (46.58%), respectively (Figure 1). The Cox proportional hazards regression technique analysis of different pre transplant variables with overall survival

**Table I.** Age group and gender distribution of study participants

| Age Group (years) | Gender | | Total | P-value |
|---|---|---|---|---|
| | Male | Female | | |
| < 9 | 4 (66.67%) | 2 (33.33%) | 6 (100%) | 0.677 |
| 10 – 19 | 11 (73.33%) | 4 (26.67%) | 15 (100%) | |
| 20 – 29 | 14 (60.87%) | 9 (39.13%) | 23 (100%) | |
| 30 – 39 | 8 (57.14%) | 6 (42.86%) | 14 (100%) | |
| 40 – 49 | 7 (53.85%) | 6 (46.15%) | 13 (100%) | |
| 50 – 59 | 3 (37.50%) | 5 (62.50%) | 8 (100%) | |

**Table II.** Demographic and clinical characteristics of transplanted AML patients

| Characteristics | | Frequency | Percentage (%) |
|---|---|---|---|
| Age Group | < 14 years | 12 | 15.18% |
| | ≥ 14 years | 67 | 84.81% |
| Gender | Male | 47 | 59.49% |
| | Female | 32 | 40.51% |
| Remission state pre-transplant | CR2 | 76 | 96.21% |
| | CR1 | 3 | 3.79% |
| FAB | M0 | 10 | 12.66% |
| | M1 | 3 | 3.80% |
| | M2 | 14 | 17.72% |
| | M3 | - | - |
| | M4 | 12 | 15.19% |
| | M5 | 16 | 20.25% |
| | M6 | 3 | 3.80% |
| | M7 | 1 | 1.27% |
| | Unknown | 20 | 25.32% |

which shows that disease status pre-transplant whether in complete and cytogenetic whether good or poor is significantly associated with overall survival in these patients. Table V-VI, Chronic GVHD was one of the transplanted related factors, found to be significantly associated with overall survival.

## DISCUSSION

A series of 79 allotransplanted Iraqi acute myeloid leukemia patients have been followed at the Iraqi specialized Center of Bone Marrow Transplant Medical city, regarding the indications, course and outcome of transplantation in form of overall survival.

The study demonstrates an overall survival (OS) in 1 year, 2 years and 3 years post-operative is 63.20% , 55.09% and 46.58% respectively. Several similar studies have been done in different countries worldwide studying the outcome of transplanted AML patients. One of them was in Italy carried out by Todisco et.al., studying the factors predicting outcome after allogenic transplant in refractory acute myeloid leukemia with a one year, 2 years and 3 years with OS of 63%, 31% and 17% respectively [7].

Another study was done in Malaysia by Ernest et al., who studied the prognosis and outcome of Malaysian transplanted AML patients demonstrating a 2 years OS of 68.4%(28). A third study was done in China by Zhu et al., also dealing with the outcome and prognosis of Chinese patient diagnosed with high risk AML who were allotransplanted with a 3 years OS of 57.55% [8]. Further two similar studies were carried out; one by the Center International Bone Marrow Transplant Research (CIBMTR) that studied the late effect of allogeneic stem cell transplantation in adolescents and adults with acute myeloid leukemia with a 2 years OS of 93% [9] and the other by European society of Bone Marrow Transplantation (EBMT) which compared the outcome of allogeneic HSCT for secondary and de novo AML patients demonstrating a three year OS for de novo AML of 54.6% [10].

In Brazil, Rodrigues et al. studied the outcome of allotransplantation in children and adolescents who had been diagnosed with AML, revealing a one, two and three years OS of 62% , 58% and 50% respectively [11)]. Canadian study done by Dalhousie university also revealed a one and three years OS for relapsed AML patients post allo-transplantation of 60% and 45.5% respectively [12]. In the local district, similar studies were done in different

**Table III.** Pre-transplant and transplant patients characteristics

| Characteristics | | Frequency | Percentage (%) |
|---|---|---|---|
| MRD | Positive | 4 | 5.06% |
| | Negative | 3 | 3.79% |
| | Not done | 72 | 91.13% |
| Cytogenetic | Favorable | 7 | 8.8% |
| | Unfavorable | 34 | 43.03% |
| | Not available | 38 | 48.10% |
| Donor characteristics | | | |
| HLA compatibility | Fully compatible | 72 | 91.14% |
| | Not-fully compatible | 5 | 6.33% |
| | No data available | 2 | 2.53% |
| ABO compatibility | Compatible | 45 | 56.96% |
| | Not compatible | 26 | 32.91% |
| | No data available | 8 | 10.13% |
| Donor gender | Male | 42 | 53.16% |
| | Sex matched | 25 | 31.64% |
| | Not sex matched | 17 | 21.51% |
| | Female | 29 | 36.71% |
| | Sex matched | 11 | 13.92% |
| | Not sex matched | 18 | 22.78% |
| | No data available | 8 | 10.13% |
| Stem cell source | Peripheral blood | 67 | 84.81% |
| | Bone marrow | 9 | 11.39% |
| | Not available | 3 | 3.80% |
| Transplant characteristics | | | |
| Conditioning regimen | Myeloablative | 56 | 70.89% |
| | Non myeloablative | 6 | 7.59% |
| | No data available | 17 | 21.52% |
| Indication of transplant | Relapsed after CR1 | 14 | 17.72% |
| | Refractory | 50 | 63.29% |
| | MRD +ve | 3 | 3.79% |
| | Poor cytogenetics | 11 | 13.92% |
| | Secondary | 1 | 1.26% |
| Duration from diagnosis to transplant | Less than 1year | 46 | 58.22% |
| | 1-2 year | 19 | 24.05% |
| | More than 2 years | 7 | 8.86% |
| | Not available | 7 | 8.86% |

**Table IV.** Causes of death of the study participants

| Cause of Death | Frequency | Percentage (%) |
|---|---|---|
| Relapse | 19 | 51.35% |
| Sepsis | 11 | 29.73% |
| Respiratory failure | 4 | 10.81% |
| Graft-vs-host-disease | 2 | 5.40% |
| Cardiac arrest | 1 | 2.70% |

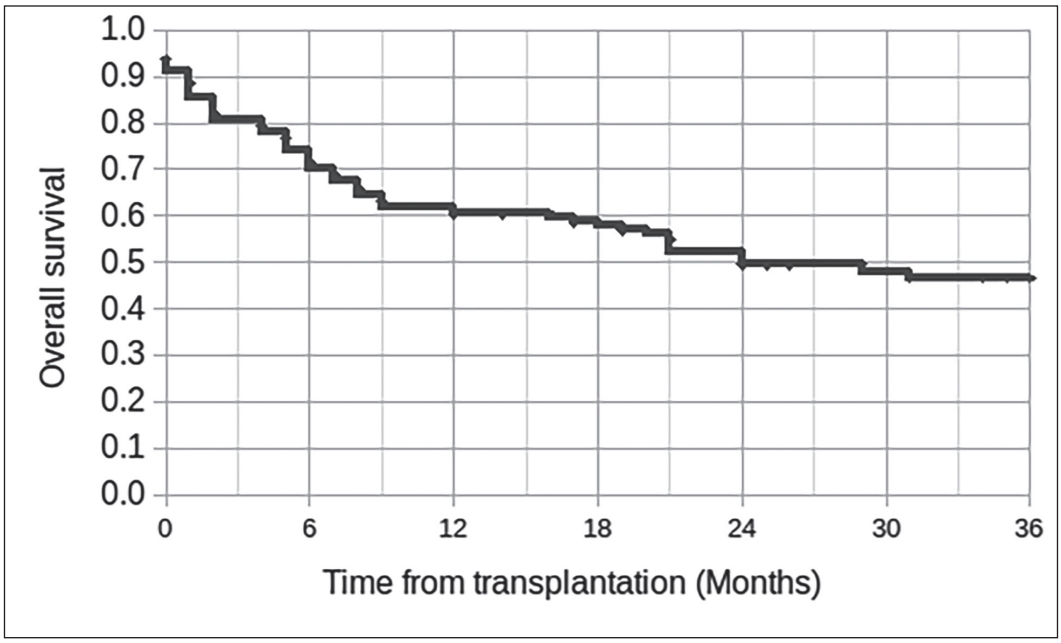


**Fig. 1**. Kaplan-Meier estimate for overall survival among study participants

**Table V.** Cox proportional hazards regression technique analysis of different pre transplant variables with overall survival

| Pre-transplant disease status | | | | | |
|---|---|---|---|---|---|
| **Factor** | | **N (%)** | **P-value** | **Hazard Ratio** | **95% C.I.** |
| Age | <14 years | 12(15.19%) | 0.7980 | 0.8907 | 0.3709-2.1385 |
| | ≥14 years | 67 (84.81%) | | | |
| Gender | Male | 47 (59.49%) | 0.9749 | 0.9900 | 0.5134-1.9090 |
| | Female | 32 (40.51%) | | | |
| FAB | M0 | 10 (12.66%) | 0.8095 | 1.0240 | 0.8441-1.2422 |
| | M1 | 3 (3.8%) | | | |
| | M2 | 14 (17.72%) | | | |
| | M3 | - | | | |
| | M4 | 12 (15.19%) | | | |
| | M5 | 16 (20.25%) | | | |
| | M6 | 3 (3.8%) | | | |
| | M7 | 1 (1.27%) | | | |
| Extra medullary involvement (CNS) | Yes | 6 (7.59%) | 0.9202 | 0.9421 | 0.2894-3.0670 |
| | No | 73 (92.41%) | | | |
| Status at transplantation | CR** | 74(93.67%) | 0.0587 | 3.9888 | 1.1868-13.4065 |
| | PR*** | 3(3.8%) | | | |
| | No data available | 2(2.5%) | | | |
| Cytogenic risk group | Favorable | 7 (8.86%) | 0.0437* | 5.0690 | 0.6725-38.2055 |
| | Unfavorable | 34 (43.04%) | | | |

* Significant at $P < 0.05$
**CR: complete remission
***Partial remission: two of patients had 10% and 8% blast cells in bone marrow with one mentioned in the report to have partial remission.

places and time periods. In Turkey, the outcome of AML allotransplanted patients was studied by Ciftciler et al. with a three years OS of 71% [13].

Ilam university of medical sciences conducted a study about the effect of GVHD on survival rate of AML allotransplanted patients giving a one year OS of 82.2% [14].

**Table VI.** Cox proportional hazards regression technique analysis of different transplant related variables with overall survival

| Factor | | N(%) | P value | Hazard ratio | 95% CI |
|---|---|---|---|---|---|
| **Donor related** | | | | | |
| **Donor Gender** | male | 42(53.16%) | 0.5774 | 0.8200 | 0.4055-1.6584 |
| | Female | 29(36.71%) | | | |
| **HLA compatibility** | Fully compatible | 72(91.14%) | 0.5248 | 0.6666 | 0.2042-2.1764 |
| | Not fully compatible | 7(8.86%) | | | |
| **ABO compatibility** | Yes | 45(56.96%) | 0.8904 | 0.9525 | 0.4763-1.9049 |
| | No | 26(32.91%) | | | |
| **Transplant related** | | | | | |
| **Stem cell source** | Peripheral blood | 67(84.81%) | 0.6672 | 0.7776 | 0.2374-2.5468 |
| | Bone marrow | 9(11.39%) | | | |
| **Conditioning regimen** | Myeloablative | 56(70.89%) | 0.4386 | 1.5586 | 0.5365-4.5282 |
| | Non-myeloablative | 6(7.59%) | | | |
| **Infection** | Yes | 36(45.57%) | 0.9499 | 0.9797 | 0.5110-1.8781 |
| | No | 43(54.43%) | | | |
| **Acute GVHD** | Yes | 15(18.99%) | 0.1690 | 1.8526 | 0.7202-4.7652 |
| | No | 64(81.01%) | | | |
| **Chronic GVHD** | Yes | 13(16.46%) | **0.0077*** | 4.6282 | 1.1119-19.2656 |
| | No | 66(83.54%) | | | |

* Significant at $P < 0.05$

In Lebanon, American University of Beirut studied the outcome of allotransplanted AML patients as a part of a general research, following all hematopoietic stem cell transplanted hematological cases demonstrating a one and three years OS of 72% and 58% respectively [15]. King Abdulaziz medical city in Saudi Arabia studied the clinical features and outcome of AML giving an overall survival for those who were allotransplanted of 72% 16].

Lastly, a large study done by Bazarbachi et al. comparing the outcome of allotransplanted AML patients in the Eastern Meditranian and European BMT centers with a three years OS for those transplanted in EMBMT of 74% compared to 73% for the EBMT group [17].

According to this study, the most common cause of death after transplantation was found to be disease relapse followed by neutropenic sepsis. Other causes include GVHD, respiratory failure, renal failure, extramedullary (central nervous system) involvement and engraftment failur . The Chinese, EBMT, Brazilian and Omanis (Sultan Qaboos university hospital study about HSCT) studies ranked disease relapse as the most common cause of death followed by infection [8, 10 , 11 , 18]. On the other hand, CIBMTR study also showed that disease relapse is the most common cause of death with GVHD as the second one and ranking post-transplant infection as a third cause [9].

The Earliest study in Malaysia revealed GVHD as the most common cause of death, followed by neutropenic sepsis [19]. The second complication was GVHD (incidence 15.9 % for each of acute and chronic GVHD), with skin manifestation being the most common followed by diarrhea and hepatic impairment. Chinese study revealed a 10.32% and 5.56% for both acute and chronic GVHD respectively, similarly presenting mostly with skin rashes, diarrhea and hepatic impairment(8). Parallelly, EBMT study observed an incidence of acute and chronic GVHD of 28.5% and 40.6% respectively [10] as well as the Italian study – 35% and 24% respectively [20].

Other complications have been noticed in this study, including graft failure, observed in 7.59%, renal disease in 6.33% , veno-occlusive disease (VOD) was seen in 5.06% and TTP that in 1.27% of patients.

Fertility problem emerged in 5.06% of the patients, which was also observed by CIBMTR study in 7 % of patients, with female being more affected than male patients [9].

In this study, analysis of correlation between different demographic factors and overall survival of transplant-

ed patients revealed that there is no significant effect of age, gender, FAB class, cytogenetic risk group, different indications of transplant, duration between diagnosis and transplantation, any of the donor characteristics, different sources of stem cells, type of conditioning regimen, incidence of infection and acute GVHD on overall survival. The presence of chronic graft host disease found to be greatly predictive in prognosing of the overall survival and association of degree of remission pre transplanted and overall survival of these patients.

Two factors had significant correlation with OS: the incidence of chronic GVHD that was also observed by Ilam and Tehran studies in Iran [14,21] and cytogenetic risk stratification that was also significantly affecting OS in the Italian, EBMT and CIBMTR studies. In the Turkish study, chronic GVHD and patient gender were found to be significantly affecting OS.

Ernest study revealed that type of conditioning regimen also significantly affect the outcome while patient`s age, source of stem cells and donor HLA matching have no significant effect [19].

The Chinese study analysis revealed that lower OS was correlated with age, infection presence, disease status at transplantation, infection and acute GVHD. Non remission state and acute GVHD also significantly affect LFS; while chronic GVHD has no significant correlation with outcome [8].

Chronic GVHD was also the predictor, effecting the OS and LFS in the study of CIBMTR [9]. From the other side, the Italian study revealed no significant effect of both acute and chronic GVHD [7].

## CONCLUSIONS

In conclusion Iraqi AML patients who were treated with allogeneic bone marrow transplant showed to have encouraging overall survival. The most common cause of death was disease relapse and chronic GVHD and cytogenetic risk stratification were found to be significantly affecting overall survival.

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**Conflict of interest:**
*The Authors declare no conflict of interest.*

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**A** – Work concept and design, **B** – Data collection and analysis, **C** – Responsibility for statistical analysis, **D** – Writing the article, **E** – Critical review, **F** – Final approval of the article