

## Results of Total Body Irradiation in Allogeneic Bone Marrow Transplantation for Acute Non-Lymphocytic Leukemia\*

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Between August 1987 and July 1991, 22 patients with acute nonlymphocytic leukemia have received allogeneic bone marrow transplantation (BMT) with non-T-lymphocyte-depleted marrow obtained from matched sibling donors. Of these patients, 12 patients were in first complete remission (CR) and 10 patients in second CR or greater or in relapse. All patients were treated with a preparative regimen consisting of cyclophosphamide (CTX, 60 mg/kg) or combined drugs, and 850 cGy single-dose or 150~200 cGy fractionated total body irradiation (TBI) administered twice daily for a total dose of 1200~1320 cGy. Survivors have been followed from 8 to 64.5 months (median, 24 months). The overall 2 year survival rate, relapse rate and incidence of radiation pneumonitis and graft versus host disease (GVHD) have been evaluated by age, phase of disease, initial WBC count, modality of TBI or conditioning chemotherapy. Overall 2 year survival was 58%. The median survival was 31 months and mean survival was 23.2 months. Overall survival have significant impact in patients of age >19 years old ( $p=0.008$ ), patients in first CR ( $p=0.09$ ). Two year survival rate is significantly correlated with age (>19 vs  $\leq 19$ , 79.4% vs 14.3%,  $p=0.0008$ ), regimen of chemotherapy (CTX vs combined drug, 76.9% vs 33.3%,  $p=0.04$ ), phase of disease (1st CR vs  $\geq 2$ nd CR or relapse, 83.3% vs 30%,  $p=0.01$ ) and method of TBI (fractionated vs single dose, 70.7% vs 37.5%,  $p=0.05$ ). The influence of French-American-British (FAB) subtypes on relapse rate is not significant, but initial WBC count  $>20000/\text{mm}^3$  is associated with increased relapse rate. There is difference in the rate of radiation pneumonitis (14.3% vs 25%), GVHD (14.3% vs 50%) and relapse (21.4% vs 50%) according to fractionated versus single-dose TBI. As mentioned above, fractionated TBI is compatible for the preparative regimen combined with chemotherapy in allogeneic BMT of first CR patients under 41 years of age with suitable donor. Those results from a retrospective, non-randomized study clearly need additional clinical data, ideally from a randomized study.

**Key Words:** Acute nonlymphocytic leukemia, Total body irradiation, Bone marrow transplantation

### INTRODUCTION

Allogeneic bone marrow transplantation (BMT) has become a well established procedure in the treatment of leukemias and other malignancies. Allogeneic BMT has developed into an effective therapy for patients with acute and chronic myeloid leukemia in prolonging remission status and improving relapse-free survival<sup>1,3,5,9,15</sup>. Unfortunately, BMT therapy of first complete remission (CR) acute nonlymphocytic leukemia (ANLL) is still associated with an actuarial death rate greater than 30% and actuarial relapse rates as high as 40% in some

series<sup>2</sup>. Long term survival and leukemic relapse with BMT in ANLL is about 50% and 25% in the first CR, and 20% and 45% in phases subsequent to first CR, respectively<sup>4</sup>. In most BMT regimens, conditioning of patients include high dose chemotherapy and total body irradiation (TBI)<sup>6,7,8,10</sup>. Success of the procedure depends on multiple contributing factors. These include the age and disease status of the recipient at the time of transplantation, development of infectious complications, graft versus host disease (GVHD) and the recurrence of leukemia. Some of these conditions reflect the effectiveness and/or toxicity of the preparative regimens that are administered to patients with the goal to ablate the leukemic clone. In earlier reports, others have made observations concerning the effects of

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recipient age, presenting peripheral WBC count, French-American-British (FAB) subtype, TBI delivery method, and other pretransplant features on outcome of BMT performed as therapy for ANLL<sup>11-14</sup>. At the present time, there is no consensus as to which TBI regimen is the most effective in reducing the relapse rate and decreasing the incidence of the acute and the late effects of treatment. In the present study dealing with 22 patients grafted for ANLL after TBI-chemotherapy conditioning regimen, we retrospectively reviewed concerning the influence of various patients characteristics and clinical events on outcome of BMT with small patient numbers.

## MATERIALS AND METHODS

### 1. Patient Characteristics

Between August 1987 and July 1991, 22 patients with newly diagnosed ANLL were treated with TBI in Catholic University Medical College St. Mary's Hospital. Twelve of these were transplanted in first complete remission; 10 received a transplant in second CR or greater or in relapse. The recipient

group consisted of 14 males and 8 females ranging in age from 10 to 40 years (median, 26.5 years). The median age of 7 recipients <20 years old was 15 years (range, 10 to 19 years), while that of 15 adults  $\geq 20$  years old was 31 years (range, 23 to 40 years). Patient characteristics are further described in Table 1. Analyses were performed as of June 1992. Follow-up of survivors ranges from 8 to 64.5 months (median, 24 months).

### 2. Treatment

Of all 22 patients, 13 were prepared with cyclophosphamide, 60 mg/kg/day, intravenously for 2 consecutive days, 9 were conditioned with other combined agents. Patients were non-randomly assigned to either single-dose TBI (8 patients) or fractionated TBI (14 patients). Median total dose was 850 cGy for single-dose TBI and 1285.7 cGy for the fractionated TBI (range 1200 to 1320 cGy). All but four patients had lung shielding bilaterally with lead blocks in the fractionated TBI. The range of dose rate was 10 to 12 cGy/min. Fractionation schemes varied, but generally delivered 1200 ~1320 cGy, mainly 150~200 cGy twice a day for 3 ~4 days. The time interval between the two daily fractions of TBI was 4~6 hr. All patients received marrow from an HLA identical sibling. Prophylaxis of GVHD consisted of either cyclosporine A (CSA), or methotrexate (MTX) or combined regimens. All patients received their TBI by 6 MV x-ray beam from linear accelerator. Details of the treatment technique and dosimetry are described in reference<sup>16</sup>.

All patients were treated with bilateral parallel-opposed fields. With the patients positioned on a specially designed TBI couch in a semifetal position, the distance from the radiation source to the sagittal axis of the patient was maintained at 4 meters. The field projected at the patient was large enough to include the entire body within the 95% isodose profile of the beam. Individualized aluminum compensators were used for head and neck, lung, and lower extremities. The attempt to shield the lung was made in 10 patients. The upper arms were positioned at the center of the lateral chest. The compensator pieces for lungs were designed by determining the equivalent thickness of the lungs plus the arms, using simulator films and physical patient measurements. No additional compensation was provided for parts of the lungs which were not covered by the arms. The data obtained from phantom dosimetry using these compensator techniques showed a dose uniformity of  $\pm 5\%$ . A 1 cm thick lucite screen was used in the

Table 1. Patient Characteristics

Age	Median Range	26.5 years 10~40 years
Sex	Male Female	14 8
WBC	Median Range	16300/mm <sup>3</sup> 600~120000/ mm <sup>3</sup>
FAB	M1 M2 M3 M4 M5 M6	4 10 1 1 4 1
CMV	Positive Negative	2 18
BM status	1st CR $\geq 2$ nd CR Relapse	12 5 5
Chemotherapy	Cyclophosphamide Combined	13 9
TBI dose	Single 850 cGy Fractionated 1200 cGy Fractionated 1320 cGy	8 4 10
Lung shield	Yes No	10 12

beam at a distance of about 20 cm from the patient's proximal surface to act as a beam spoiler, that is to build up the skin dose to the same dose as the midline dose. This was verified by phantom dosimetry as well as by thin Thermoluminescent dosimeter chips taped on the surface of selected patients. The dose specification point was determined at the level of the umbilicus. Dose monitoring was assured during every fraction by an ionization chamber, located in a small plastic phantom under the treatment couch. Lungs were shielded for 2 fractions, on days 3 or 4, with 5 half-value layer blocks bilaterally for once 1 day, without chest wall electron boost.

### 3. Statistical Analysis

Survival curves were calculated by the Kaplan-Meier method. Significance was calculated by the Log-rank and Wilcoxon test. Survival among the patients was assessed as of June 30, 1992. For statistical analysis, a series of contingency tables were constructed and evaluated using the Chi-square and Fisher exact test for small expected counts. Univariate analyses were performed by using the Kaplan-Meier product-limit method to assess the effects of various factors on survival, relapse and relapse free survival (eg, recipient age, FAB classification, initial WBC count).

## RESULTS

### 1. Survival

Eleven of 22 patients died from 8 to 31 months

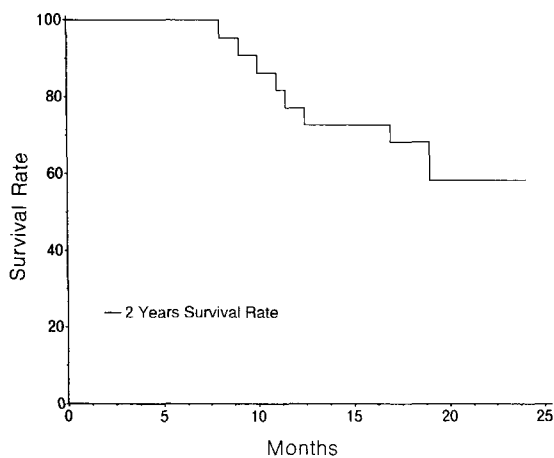


Fig. 1. Overall 2 year survival rate in acute nonlymphocytic leukemia treated with total body irradiation and allogeneic bone marrow transplantation.

following diagnosis. Kaplan-Meier estimate of survival is 58% at 2 years (Fig. 1). Median survival and mean survival were 31 months and 23.3 months, respectively. Various potential prognostic factors, including FAB classification, patient age, initial WBC count, phase of disease and preparative regimen were analyzed to determine their impact on survival. Univariate analyses revealed that patients in age  $>19$  (79.4% vs 14.3%,  $p=0.0008$ , Fig. 2), in first CR at BMT (83.3% vs 30.0%,  $p=0.001$ , Fig. 3), treated with conditioning chemotherapy including cyclophosphamide (76.9% vs 33.3%,  $p=0.04$ , Fig. 4) and receiving fractionated TBI (70.7% vs 37.5%,  $p=0.05$ , Fig. 5) were good prognostic factors for survival at 2 years. FAB subtype and initial WBC count had no significant impact on

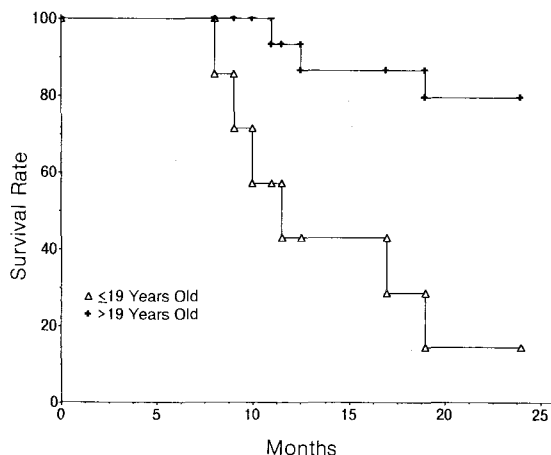


Fig. 2. Survival rate at 2 year by age of recipients.

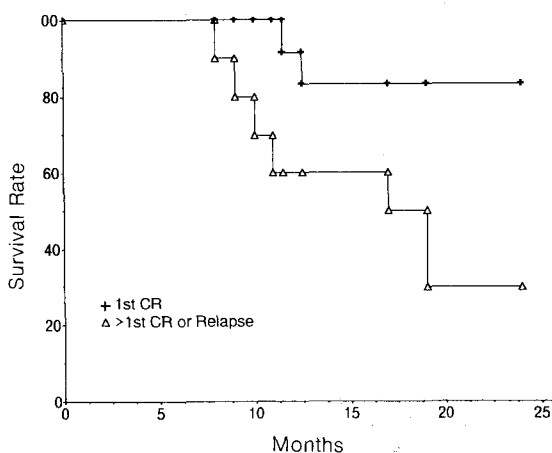


Fig. 3. Survival rate at 2 year by phase of disease.

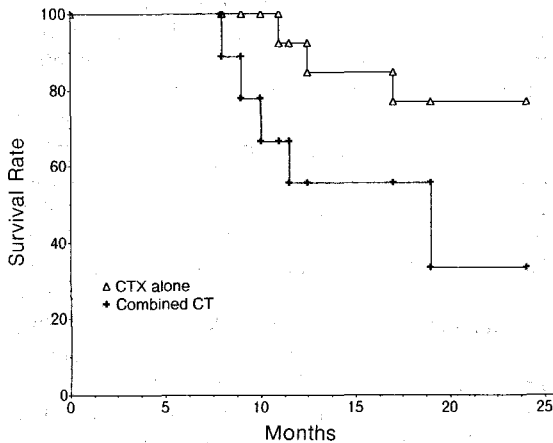


Fig. 4. Survival rate at 2 year by preparative chemotherapy.

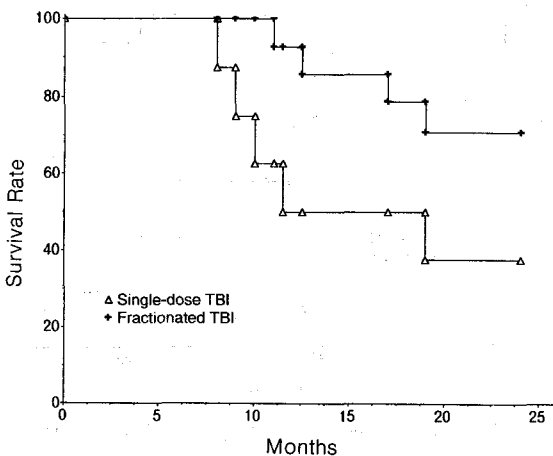


Fig. 5. Survival rate at 2 year by regimen of total body irradiation.

survival ( $p=0.87$ ,  $p=0.23$  and  $p=0.11$ ). Table 2 shows further description of the 2-year survival rates by prognostic factors.

## 2. Relapse Rate and Relapse Free Survival

Seven of 22 patients relapsed, a relapse rate of 31.8%. Additionally, single dose TBI regimen and initial WBC count  $>20000$  were associated with a higher relapse rate than others (50% vs 21.4% and 42.9% vs 22%). But FAB morphology of M4 or M5 was not associated with increase in relapse rate. There was no statistically significant impact of initial WBC count, FAB subtype, phase of disease,

Table 2. Two Year Survival Rates by Prognostic Factors

Factor	No	2-year survival (%)	p-value
Age $\leq 19$	7	14.3	0.0008
$>19$	15	79.4	
Sex M	14	56.3	0.87
F	8	62.5	
FAB* M1, 2, 3, 6	16	52.3	0.23
M4, 5	5	80.0	
WBC** $\leq 20000$	9	45.0	0.11
$>20000$	7	85.7	
CT <sup>+</sup> CTX <sup>++</sup>	13	76.9	0.04
Combined	9	33.3	
BM <sup>#</sup> 1st CR	12	83.3	0.01
$\geq 2$ nd CR or relapse	10	30.0	
TBI Single-dose	8	37.5	0.05
Fractionated	14	70.7	

\*French-American-British Subtypes (1 patient was missing)

\*\*6 patients were missing

+Chemotherapy

++Cyclophosphamide

#Bone marrow status at the time of BMT

chemotherapy drug and TBI regimen on relapse free survival.

## 3. Complications

Idiopathic interstitial pneumonitis was developed in four of 12 patients treated without lung shield (33.3%) and revealed higher incidence in single dose TBI than fractionated TBI (25% vs 14.3%). There was a higher incidence of GVHD among single dose TBI than among fractionated TBI (50% vs 14.3%).

## DISCUSSION

Our present analysis demonstrates that there is a difference in survival and disease control for different regimens of TBI method. Although some investigators advocate conditioning regimens using chemotherapy alone for allogeneic BMT for ANLL<sup>17</sup>, most investigators use a combination of high dose chemotherapy and TBI to prepare these patients<sup>1,6,7</sup>. TBI in allogeneic BMT for ANLL is used to kill a maximal number of leukemic stem cells while limiting toxicity to acceptable levels in non-leukemic tissues, and to eradicate the recipient bone marrow and immunocompetent cells to allow engraftment<sup>18,19</sup>. A comparison of recipients  $\leq 19$

years old with those >19 years old shows that adults >19 years old had a high survival rate at 2 year and relapse free survival rate. Among patients >19 years old, recipients between the ages of 20 and 29 years revealed the highest survival. These findings differ from those of Clift et al. who reported a significant trend of decreasing disease-free survival with increasing age in univariate analysis, although the rate of decrease with advancing age was slightly above the age of 20 years<sup>14</sup>). The finding of equivalent survival in younger and older recipients, however, agrees with an earlier report of the International Bone Marrow Transplant Registry<sup>20</sup>) and with a more recent report in which no significant adverse effect of recipient age (range of 1 to 41 years) on disease-free survival posttransplant for first CR from ANLL could be demonstrated<sup>13</sup>).

In this study, several presenting patient characteristics affected the outcome of BMT. But the relapse rate seen in recipients presenting with morphologic evidence of a monocytic component (FAB M4, M5) was not significantly higher than that in patients presenting with other FAB subtypes. Although an increased relapse rate in patients presenting with FAB M4 or M5 morphology has been reported after conventional therapy<sup>21-23</sup>) and after BMT<sup>11,12</sup>), no such correlation could be found in a recent report of BMT for first CR from ANLL in children<sup>7</sup>) and in two recent studies of BMT therapy of ANLL in young adults<sup>13,14</sup>). The finding of a higher post-BMT relapse rate in patients presenting with a monocytic subtype of ANLL suggests that preparation for BMT with additional agents known to have antitumor activity may be useful in this situation<sup>24</sup>). The patients with a peripheral WBC count >20000/mm<sup>3</sup> had insignificant impact on survival and relapse free survival. Relapse rate in these patients was higher than that in patients with initial WBC count  $\leq$ 20000/mm<sup>3</sup>. The finding of a correlation between a high presenting peripheral WBC count and poor disease-free survival have reported in other observations<sup>12</sup>). However, Clift et al. could not demonstrate a correlation between presenting WBC count and disease-free survival<sup>14</sup>). Similarly, Forman et al. found no relationship between peripheral WBC count and outcome after BMT therapy for first CR from ANLL<sup>13</sup>). The most ideal TBI regimen in BMT for acute leukemia would be the regimen that achieves the maximum therapeutic ratio, that is, the maximum target cell kill with minimum damage to the normal tissue. Target cells include leukemic cells, leukemic stem cells, and cells responsible for immune function. The group at

Fred Hutchinson Cancer Center pioneered BMT for acute leukemia using high dose chemotherapy and a single fraction of 1000 cGy TBI at a dose rate of 5 cGy/minute<sup>1</sup>). Some investigators, however, contend that fractionated or hyperfractionated TBI is a better method than single fraction TBI because leukemic cells have a very narrow shoulder of the radiation cell survival curve, indicating that they have a very limited capability to repair sublethal damage<sup>25-28</sup>). These investigators postulate that fractionated or hyperfractionated TBI maximizes leukemic cell kill with minimal damage to the normal tissue. Other investigators, however, have demonstrated that the survival curve for some acute leukemia cells are not different from those for normal or other malignant cells<sup>29</sup>). In this result, the patients receiving fractionated TBI have shown a significant trend of improvement of Kaplan-Meier survival rate at 2 year. The relapse rate and incidence of idiopathic interstitial pneumonitis were lower in fractionated TBI than in single dose TBI. The lower rate of recurrence in fractionated TBI regimen was not correlated with other study<sup>30-33</sup>). The number of patients are too small and follow-up time too short. In conclusion, our study showed that allogeneic BMT with TBI preparation is an effective treatment in prolonging survival time in patients with ANLL in the first remission. To improvement the results by reducing the recurrence rate using fractionated TBI on a small number of patients has not shown significant impact, although there is a statistically insignificant trend of improvement in favor of fractionated TBI. Further study will be needed to define better TBI regimens.

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== 국문초록 ==

### 급성 골수성 백혈병에서 동종골수이식을 위한 전신 방사선 조사의 치료 결과

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1987년 8월부터 1991년 7월까지 급성골수성 백혈병으로 가톨릭대 치료방사선과에서 동종골수 이식을 위한 전신방사선치료를 받은 22명의 환자를 대상으로 성별, 연령, 골수이식당시병기, FAB 아형, 초기말초혈액백혈구수, 항암치료방법, 방사선치료방법에 따라 2년 생존율, 2년무병생존율, 재발율과 간질성폐염 및 이식편대숙주병 (GVHD)의 발생빈도를 후향분석하였다.

22명중 12명은 제 1 완전관해기, 10명은 제 2 완전관해기이후 혹은 재발기였으며, 모든 환자들은 HLA 완전일치의 동종골수이식을 위한 전처치로 다제병용화학요법과 전신방사선조사가 시행되었다.

화학요법은 13명에서는 cyclophosphamide (60 mg/kg) 단독으로, 9명에서는 복합화학요법으로 시행되었으며 전신방사선조사는 8명에서는 850 cGy를 1일 1회로 단일조사되었고, 14명에서는 150~200 cGy를 1일 2회 분할조사하여 3~4일간 총 1200~1320 cGy로 치료되었다. 추적관찰기간은 8개월에서 64.5개월로 중간값은 24개월이었다. 전체 환자의 2년 생존율은 58%였으며 중간생존기간은 31개월이었고 평균 생존기간은 23.2개월이었다. 2년 생존율은 환자의 연령이 20세 이상인 경우가 20세 미만인 경우보다 높게 나타났으며 (79.4% vs 14.3%,  $p=0.0008$ ), 전신방사선치료 및 골수이식이 완전관해기에 시행된 경우가 제 2 관해기 이후 혹은 재발기에 시행된 경우보다 2년 생존율이 높게 나타났다 (83.3% vs 30%,  $p=0.01$ ). 화학요법이 cyclophosphamide 단독으로 시행된 경우 병용화학요법이 시행된 경우보다 2년 생존율이 더 좋았으며 (76.9% vs 33.3%,  $p=0.04$ ), 전신방사선조사는 분할조사로 치료된 군에서 1일 1회 단일조사를 받은 군보다 2년 생존율이 높게 나타났다 (70.7% vs 37.5%,  $p=0.05$ ).

재발율에 있어서 FAB 아형은 유의한 차이를 보이지 않았으나, 초기말초혈액 백혈구 수는 20000/ $\text{mm}^3$  이상인 경우 이하인 경우보다 재발율이 높게 나타났다 (42.9% vs 22.0%). 또한 방사선치료방법에 따라 재발율과 방사선폐렴 및 이식편대숙주병 빈도를 조사한 결과 분할조사시 재발율이 낮게 나타났다 (21.4% vs 50.0%), 방사선에 의한 폐렴 및 이식편대 숙주병의 빈도도 낮게 나타났다 (14.3% vs 25.0%, 14.3% vs 50.0%). 이로써 HLA 일치혈연자중 골수공여자가 있는 제 1 완전관해기의 급성골수성백혈병환자에서 동종골수이식을 위한 전처치로써 화학요법과 함께 전신방사선 분할조사는 중요한 역할을 담당함을 알 수 있었으나 보다 많은 환자를 대상으로 한 전향적 연구가 필요할 것으로 사료된다.