

Autologous hematopoietic stem cell transplantation in chemotherapy-sensitive lymphoblastic lymphoma: treatment outcome and prognostic factor analysis

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Objective: The study evaluated the effectiveness of autologous hematopoietic stem cell transplantation (AH SCT) in the treatment of lymphoblastic lymphoma (LL).

Methods: We retrospectively analyzed the data from 41 patients with chemotherapy-sensitive LL who underwent hematopoietic stem cell transplantation (HSCT) from December 1989 to December 2009 in a single institution.

Results: HSCT was conducted as first-line consolidation therapy and salvage therapy in 36 and 5 patients, respectively. The median follow-up was 97.1 months (range, 24.6-173.1 months). The 5-year overall survival (OS) and event-free survival (EFS) rate were 64% and 47% for the initially treated patients, respectively, and were both 20% for the relapsed ones. Bone marrow (BM) involvement and chemotherapy cycles prior to transplantation were identified as significant prognostic factors for EFS in multivariate analysis.

Conclusions: These results confirm that AH SCT is a reasonable option for chemotherapy-sensitive LL patients in first complete remission (CR1).

Keywords: Lymphoblastic lymphoma (LL); high-dose therapy (HDT); hematopoietic stem cell transplantation (HSCT); autologous; allogeneic

Submitted Oct 01, 2014. Accepted for publication Jan 23, 2015.

doi: 10.3978/j.issn.1000-9604.2015.02.04

View this article at: <http://dx.doi.org/10.3978/j.issn.1000-9604.2015.02.04>

Introduction

Lymphoblastic lymphoma (LL) is a relatively infrequent malignancy, constituting approximately 2% of non-Hodgkin's lymphoma (NHL) (1), which is common among adolescent and young adult males (2). A mass in the anterior mediastinum is common at diagnosis and bone marrow (BM) and/or central nervous system (CNS) involvement is also usually seen during the course of the disease (3).

The results of standard cyclophosphamide, doxorubicin, vincristine and prednisone (CHOP)-based chemotherapy

regimens are disappointing (3,4). The intensive protocols for acute lymphoblastic leukemia (ALL) are now proved to be more appropriate for LL with long-term survival rates from 51.0% to 86.5% (5-7). Due to a high chance of complete remission (CR) and subsequent relapse, a high-dose therapy followed by the hematopoietic stem cell transplantation (HDT/HSCT) has also been explored to consolidate remission in LL patients with some supportive evidences (8-12). So far, for adult LL patients, only one prospective randomized trial has been conducted to compare

HDT/HSCT with the normal-dose consolidation regimens as post-remission therapy (11). The study suggested that the use of HDT/HSCT in the first remission produced a trend of improved progression-free survival (PFS) rate, whereas it did not improve overall survival (OS) rate. Therefore, more research is needed to evaluate whether HDT/HSCT could improve the survival of the selected appropriate LL patients. The aim of the present study was to assess the effectiveness of autologous hematopoietic stem cell transplantation (AHSCT) in chemotherapy-sensitive LL and to analyze the potential prognostic factors on survival.

Materials and methods

Patients

From December 1989 to December 2009, 120 LL patients received chemotherapy in Cancer Institute/Hospital, Chinese Academy of Medical Sciences (CAMS) & Peking Union Medical College (PUMC), 41 of which were treated with HDT/HSCT when effective remission was achieved. In this retrospective study, we collected the data from the BM and peripheral blood stem cell (PBSC) data registry of our institution.

The study was approved by the Ethics Committee and the Human Research Committee of the CAMS & PUMC. Informed consent from all adult patients and guardians of underage patients was obtained for chemotherapy, radiotherapy and HDT/HSCT related procedures.

The diagnosis of all the patients was confirmed by histological examination, and lymphocyte origins were established by immunohistochemistry. Physical examination, computed tomography (CT) of the neck, chest, abdomen and pelvis, BM aspiration and/or biopsy, and lumbar puncture were involved in staging assessment, and clinical stages were defined according to the Ann Arbor system (13). Before treatment, all patients underwent routine blood test and blood biochemical test. In our center, the patients who were more than 60 years old or had an Eastern Cooperative Oncology Group (ECOG) performance score greater than 2 were considered to be not eligible for HDT/HSCT. The patients who had ALL (more than 25% BM blasts cells), any severe cardiac, pulmonary, hepatic or renal dysfunction, or human immunodeficiency virus (HIV) infection were also excluded from this study.

Induction therapy

CHOP-based protocols, including CHOP, cyclophosphamide,

doxorubicin/epirubicin, vincristine, etoposide and prednisone (CHOEP), bleomycin, epirubicin, cyclophosphamide, vincristine and prednisone (BACOP) and prednisone, cyclophosphamide, doxorubicin, etoposide, cytarabine, bleomycin, vincristine and methotrexate (proMACE-CytaBOM), were used for induction before 2004, and fractionated cyclophosphamide, vincristine, adriamycin, and dexamethasone (hyper-CVAD) regimen was taken thereafter. Besides, dexamethasone, ifosfamide, carboplatin and etoposide (DICE) and ifosfamide and topotecan (IT) regimens were also used for rescue. Only one CD20 positive B-LL patient received rituximab during both induction and consolidation period. At least 2 cycles (range, 2-7 cycles) of induction chemotherapy were offered to each patient. CNS prophylaxis included intrathecal 10 mg methotrexate and 5 mg prednisolone or 50 mg cytarabine and 5 mg prednisolone for 6-8 times in 6-12 weeks. For the patients with CNS involvement at diagnosis, the intrathecal treatments above were administered till the results of cerebrospinal fluid test returned to normal level and then additional intrathecal injections should be repeated for 2-4 times.

High-dose therapy (HDT)

High-dose consolidation was performed on the patients who achieved at least partial response (PR) from induction or rescue chemotherapy. The consolidation regimens were divided into two kinds of protocols: one is total body irradiation (TBI)-based therapy, and the other is simple high-dose chemotherapy including the following regimens: CBV (cyclophosphamide 1.8 g/m², carmustine 450-600 mg/m² and etoposide 900-1,600 mg/m²), BEAC (carmustine 300 mg/m², etoposide 800 mg/m², cytarabine 1,600 mg/m² and cyclophosphamide 1.8 g/m²), BEAM (carmustine 300 mg/m², etoposide 800 mg/m², cytarabine 1,600 mg/m² and melphalan 140-160 mg/m²), BEAM-R (BEAM and rituximab 375 mg/m²) and ACM (cytarabine 1,600 mg/m², carboplatin 500-800 mg/m² and mitoxantrone 50 mg/m²).

Hematopoietic stem cell transplantation (HSCT)

The patients with BM involvement and available human leukocyte antigen (HLA)-identical donors received allogeneic hematopoietic stem cell transplantation (allo-HSCT), and the rest ones accepted AHSCT. During the period of 20 years, graft types changed from BM to PBSC. No *ex vivo* purging was carried out in this study.

Table 1 Patients' characteristics

Parameter	Total	CR1	Other disease status
No. of patients [%]	41	26 [63]	15 [37]
Age (year)			
Median	19	19	19
Range	7-56	7-56	7-36
Sex, n [%]			
Male	33 [80]	19 [73]	14 [93]
Female	8 [20]	7 [27]	1 [7]
Immunophenotype, n [%]			
T-lymphoblastic lymphoma	34 [83]	22 [85]	12 [80]
B-lymphoblastic lymphoma	7 [17]	4 [15]	3 [20]
Ann Arbor Stage at diagnosis, n [%]			
I	5 [12]	4 [15]	1 [7]
II	14 [34]	10 [39]	4 [27]
III	4 [10]	2 [8]	2 [13]
IV	18 [44]	10 [39]	8 [53]
B symptom, n [%]	15 [37]	8 [31]	7 [47]
ECOG performance status, n [%]			
0	18 [44]	13 [50]	5 [33]
1	22 [54]	12 [46]	10 [67]
2	1 [2]	1 [4]	0 [0]
Mediastinal involvement, n [%]	30 [73]	18 [69]	12 [80]
Extra nodal involvement, n [%]	24 [59]	15 [58]	9 [60]
BM involvement, n [%]	8 [19]	4 [15]	4 [27]
CNS involvement, n [%]	7 [17]	3 [12]	4 [27]
Pleural/pericardial effusion, n [%]	12 [29]	9 [35]	3 [20]
High LDH at diagnosis, n [%]	17 [42]	10 [39]	7 [47]
High β 2-M at diagnosis, n [%]	11 [27]	10 [39]	1 [7]

ECOG, Eastern Cooperative Oncology Group; BM, bone marrow; CNS, central nervous system; LDH, lactate dehydrogenase; β 2-M, β 2-microglobulin.

Post-transplantation radiotherapy

Post-transplantation radiotherapy (40-50 Gy) was offered to the patients with mediastinum mass at diagnosis or residual disease at transplantation.

Evaluation of clinical response

Response to treatment was evaluated according to

International Workshop Criteria (14), which was based on physical examination and radiological test. CR1 or PR1 was defined as CR or PR from the first-line therapy, and CR2 defined as CR from the rescue therapy.

Follow up and statistical analysis

The SPSS 20.0 software (SPSS Inc., Chicago, USA) was used. Patient characteristics were described as median and range, or proportion. Telephone visitation was used for follow-up inspection. The last follow-up date was November 26th, 2013. OS referred to period between diagnosis and death of any causes or the last-follow up for the surviving patients. Event-free survival (EFS) started from the first day of induction and ended at the date of disease progression or relapse, or death due to any causes, whichever happened first. Survival was analyzed according to the Kaplan-Meier method, and survival variables were compared between groups using the log-rank test. Multivariate analysis with variable significant was performed with the Cox proportional hazard regression model. All P values were 2-sided and P<0.05 was considered statistically significant.

Results

Patient characteristics

Between December 1989 and December 2009, 41 LL patients were enrolled in the study. HDT/HSCT was conducted as consolidation after initial therapy in 36 patients and as salvage therapy in 5 ones. All patients' clinical characteristics at diagnosis are summarized in *Table 1*. Median age was 19 years old, and there was a male predominance. There were 34 patients (83%) of T-LL subtype and 7 (17%) of B-LL subtype. There were 18 patients (44%) at stage IV, with pleural or pericardial effusion in 12 patients, BM involvement in 8 patients and CNS involvement in 7 patients. Other extra-nodal involvements included spleen (3 patients), skin or kidney (2 patients each), and adrenal gland, breast, testis or gastrointestinal tract (1 patient each). At diagnosis, 17 (42%) and 11 (27%) patients had elevated plasma lactate dehydrogenase (LDH) levels and β 2-microglobulin (β 2-M) levels, respectively (*Table 1*).

Before 2004, 24 of the 36 (88%) initially treated patients received CHOP-based induction regimens. And 5 relapsed cases (12%) were rescued by proMACE-CytaBOM (2 patients), or hyper-CVAD, DICE or IT regimen (1 patient

Table 2 Transplantation- related factors (N=41)	
Parameter	n (%) or median [range]
Disease status at transplantation	
CR1	26 (63.4)
CR2	10 (24.3)
PR1	5 (12.2)
No. of prior chemotherapy cycles	4 [2-7]
Graft type	
Bone marrow	5 (12.2)
Peripheral blood stem cell	34 (82.9)
Both	2 (4.9)
Graft source	
Autologous	38 (92.7)
Allogeneic	3 (7.3)
Purging	0 (0)
Conditioning regimens	
TBI based	14 (34.1)
CBV	5 (12.2)
BEAC	16 (39.0)
BEAM	4 (9.8)
BEAM-R	1 (2.4)
ACM	1 (2.4)
Radiotherapy post-HSCT	13 (31.7)

CR, complete remission; PR, partial remission; TBI, total body irradiation; CBV, cyclophosphamide, carmustine and etoposide; BEAC, carmustine, etoposide, cytarabine and cyclophosphamide; BEAM, carmustine, etoposide, cytarabine and melphalan; BEAM-R, carmustine, etoposide, cytarabine, melphalan and rituximab; ACM, cytarabine, carboplatin and mitoxantrone; HSCT, hematopoietic stem-cell transplantation.

each). The median number of prior chemotherapy cycles was 4 (range, 2-7).

At transplantation, there were 26 (63.4%) patients of CR1, 10 (24.3%) of CR2 and 5 (12.2%) of PR1. Hematopoietic stem cell types used included: PBSC in 34 cases, BM in 5 cases, and both PBSC and BM in 2 cases. Post-transplantation radiotherapy was accomplished in 13 patients (Table 2).

Remission duration and survival

All patients accomplished engraftment successfully, without

treatment-related mortality (TRM). With a median follow-up of 97.1 months (range, 24.6-173.1 months) for the surviving patients, the estimated 5-year OS and EFS were 64% and 47% for the 36 initially treated patients, respectively, and they were both 20% for the 5 relapsed patients (Figure 1).

Survival according to status at transplantation

The patients who underwent HDT/HSCT at CR1 had superior outcomes compared to those at other status in terms of 5-year OS (73% vs. 33%, $P=0.033$), and tended to show better outcomes in 5-year EFS (49% vs. 33%, $P=0.076$) (Figure 2).

Survival of BM involved patients

There were eight patients presenting with disease at BM, of which, three underwent allo-HSCT and remained disease-free during the follow up of 25, 40 and 144 months, respectively, while the other five received AHST and all died of disease progression within 25 months after the transplantation.

Prognostic factors

In univariate analysis, there was no statistically significant difference in OS and EFS for any of the following variables: sex, immunophenotype, Ann Arbor stage, B symptom, CNS involvement, pleural/pericardial effusion, high LDH, high $\beta 2$ -M, induction regimens, TBI in consolidation and post-HSCT radiotherapy. BM involvement ($P=0.047$) and the number of prior chemotherapy cycles (4 cycles as cut-off) ($P=0.015$) were indicated to be significant predictors for EFS. The only significant factor of OS was CR1 status at transplantation ($P=0.033$) (Table 3).

Multivariate analysis demonstrated that BM involvement [$P=0.016$; hazard ratio (HR): 3.283; 95% confidence interval (95% CI): 1.250-8.623] and the number of prior chemotherapy cycles (<4 cycles) ($P=0.026$; HR: 3.201; 95% CI: 1.149-8.913) affected EFS significantly. The patients who underwent transplantation at CR1 status showed a trend towards a longer OS ($P=0.070$) (Table 4).

Discussion

In this single-center retrospective study, we described the long-term outcomes of a selected series of LL patients

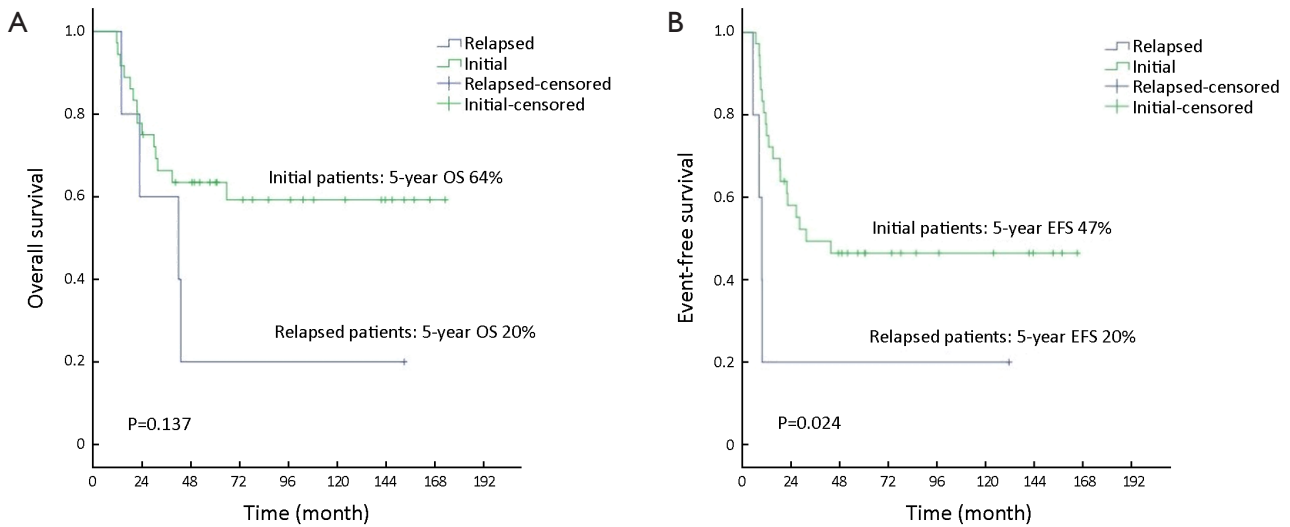


Figure 1 OS (A) and EFS (B) of initially treated and relapsed patients. OS, overall survival; EFS, event-free survival.

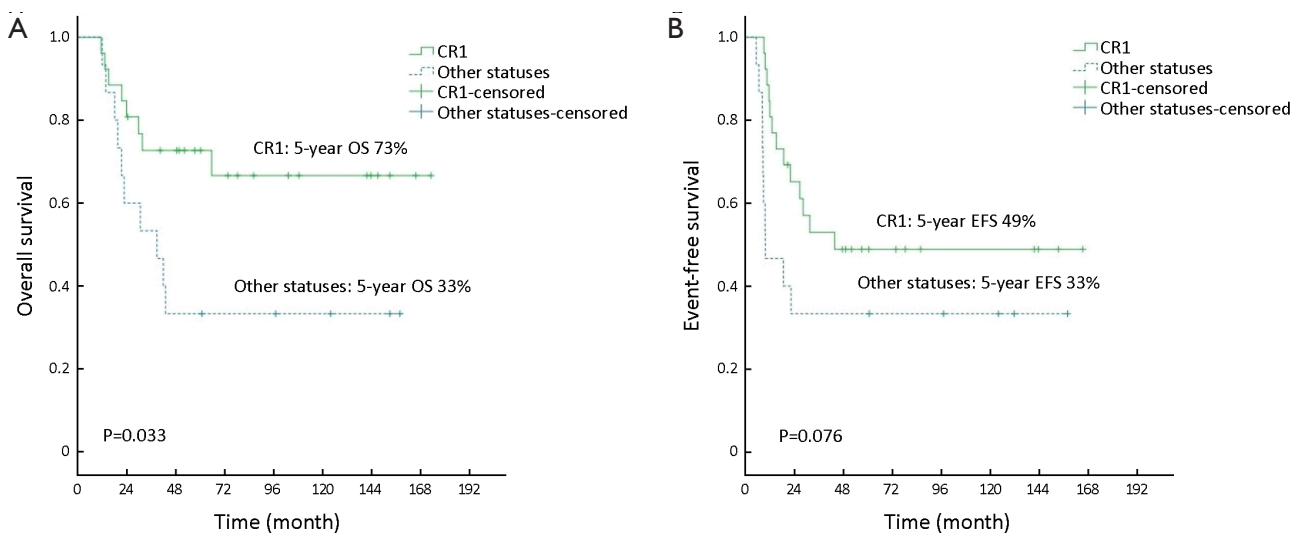


Figure 2 OS (A) and EFS (B) according to disease status at transplantation: CR1 vs. other statuses. OS, overall survival; EFS, event-free survival; CR1, first complete remission.

treated with HDT/HSCT. Our results confirmed that HDT/HSCT is effective for chemotherapy-sensitive LL patients, and the best timing for transplantation is CR1.

Of all the 41 patients in this study, 23 achieved a long-term disease control, and nearly 80% of them were at CR1 at transplantation. The patients who received HDT/HSCT at CR1 attained a 5-year OS of 73%, which was similar to the most favorable outcomes of adults reported in previous literatures. An intention-to-treat analysis concluded that a planned consolidation with HDT/HSCT in the first

response resulted in favorable long-term outcomes, with a 4-year OS of 79% (9). The largest series of HDT/HSCT in LL (n=214) were reported by the European Group for Bone Marrow Transplantation: a 6-year actuarial OS was 63% for the patients transplanted at CR1 (15). Furthermore, the long-term survival seemed superior to those achieved by ALL protocols for adults. The German Multicenter Study Group for adult ALL (GMALL) reported a 7-year OS of 51% in adults with T-LL treated by ALL protocols (6). Another study demonstrated that a 3-year OS of 70% was

Table 3 Univariate analysis of predictive factors influencing survival

Prognostic factor	N	5-year OS		5-year EFS	
		%	P	%	P
Male	33	55	0.275	45	0.916
T-LBL	34	58	0.783	41	0.574
Ann Arbor stage IV	18	48	0.324	33	0.188
B symptom	15	57	0.858	45	0.915
BM involvement	8	23	0.175	13	0.047*
CNS involvement	7	57	0.979	57	0.475
Pleural/pericardial effusion	12	58	0.880	50	0.947
High LDH at diagnosis	17	52	0.472	41	0.627
High β 2-M at diagnosis	11	55	0.846	36	0.403
Hyper-CVAD regimen	12	67	0.453	58	0.280
CR1 at transplantation	26	73	0.033*	49	0.076
<4 cycles of prior chemotherapy	10	50	0.613	20	0.015*
TBI in consolidation	14	57	0.657	36	0.410
Radiotherapy post-HSCT	13	69	0.655	46	0.719

*, P<0.05. T-LBL, T lymphoblastic lymphoma; BM, bone marrow; CNS, central nervous system; LDH, lactate dehydrogenase; β 2-M, β 2-microglobulin.

Table 4 Multivariate analysis of predictive factors influencing survival

Parameter	OS			EFS		
	HR	95% CI	P	HR	95% CI	P
Bone marrow involvement	2.011	0.652-6.204	0.224	3.283	1.250-8.623	0.016
CR1 at transplantation	2.465	0.928-6.549	0.070	1.436	0.572-3.607	0.441
<4 cycles of prior chemotherapy	1.191	0.376-3.772	0.766	3.201	1.149-8.913	0.026

HR, hazard ratio; 95% CI, 95% confidence interval.

achieved by hyper-CVAD regimen in adults (7). Besides the effectiveness of HDT/HSCT, the encouraging survival results in our study may have been influenced by the patient selection. Firstly, only the chemotherapy-sensitive patients who achieved at least PR status before transplantation were enrolled in our study. Secondly, the case series contained some children and relatively younger adults, with the median age of 19 years old. Patients younger than 20 years old may have better outcomes (4). Thirdly, all patients except one in our study had an ECOG performance status of 0 or 1 who may have a better tolerance to chemotherapy.

The 5-year EFS of patients at CR1 was 49%, which was likely inferior to the results published in the previous studies assessing HDT/HSCT or protocols for ALL in adults with LL (6,7,9-12). In our study, of the 26 patients

in CR1, 17 (65%) were induced by CHOP-based regimens, which were not effective enough for LL later (8,16,17). That may contribute to the relatively poor disease control. In addition, multivariate analysis demonstrated that EFS was significantly affected by the number of prior chemotherapy cycles (4 cycles as cut-off), indicating that intensive chemotherapy protocols and adequate treatment duration were required for ideal disease control. Therefore, efforts had to be made in frontline therapy. An eight-drug intensive induction chemotherapy regimen was reported in children with T-LL, which achieved good outcomes (5-year EFS, 90%). The regimen included L-asparaginase, high-dose methotrexate, moderate cumulative doses of anthracyclines (240 mg/m²) and cyclophosphamide (3 g/m²), and efficacious CNS prevention (18). It was suggested

that such intensive multi-drug regimens deserved more exploration in adults.

Of the 23 patients who suffered disease progression after HDT/HSCT, 5 responded to rescue therapies and achieved long survival. For those inherent chemotherapy-sensitive LL patients, second allogeneic or autologous HSCT was reported to be feasible (19,20). A retrospective study with the largest series suggested that a second AHST (AHST2) should be considered for the patients with relapsed Hodgkin's lymphoma (HL) or NHL after a prior AHST (AHST1). The outcomes were encouraging, with a lower TRM than what was reported for allogeneic transplantation in that setting (20). In our series, one patient who relapsed after AHST1 underwent AHST2 in CR2, and got a long disease-free survival, suggesting that AHST2 could be a reasonable option for LL patients and its role remains to be evaluated by more evidences.

In our study, BM involvement was considered as an important prognostic factor for EFS, which was similar to those previous researches (4,9,21). In the patients with BM involvement, those who underwent allo-HSCT achieved obvious longer survival than those who received AHST. The finding suggested that for the patients with BM involvement, especially younger patients, allo-HSCT should be the priority. However, Levine *et al.* summarized their data and found that even though allo-HSCT for LL was associated with fewer relapses than AHST, higher TRM offset any potential survival benefits (22). Therefore, further validation was required for the finding.

Conclusions

The present retrospective long-term follow-up study suggests that AHST is an effective strategy in the treatment of chemotherapy-sensitive LL patients, and CR1 is the optimal timing for transplantation, resulting in favorable survival outcomes. For the patients with BM involvement, allo-HSCT is superior to AHST. Efforts have to be made in frontline therapy and strategies for relapse after AHST1 to improve patient survival in the future.

Acknowledgements

Funding: This study was supported in part by grants from the National Technologies Research and Development Program of China during the 9th Five-Year Plan Period (A20199610396-906-01-12), the Ying Dong Fok Foundation

for Young College Teacher (B231996001), and Chinese National Major Project for New Drug Innovation (2008ZX09312, 2012ZX09303012).

Disclosure: The authors declare no conflict of interest.

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Cite this article as: Shi Y, Zhou S, He X, Han X, Wu S, Pan F, Liu P, Liu Y, Lei Y, Zhang H, Yang J, Qin Y, Zhang C, Yang S, Zhao L, Luo K, Wu G, Sun Y, Shi Y. Autologous hematopoietic stem cell transplantation in chemotherapy-sensitive lymphoblastic lymphoma: treatment outcome and prognostic factor analysis. *Chin J Cancer Res* 2015;27(1):66-73. doi: 10.3978/j.issn.1000-9604.2015.02.04