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# Ⅴ．代表的論文

Pediatr Blood Cancer 2014;61:1215–1221

# Improved Treatment Results of Children With B-Cell Non-Hodgkin Lymphoma: A Report From the Japanese Pediatric Leukemia/Lymphoma Study Group B-NHL03 Study

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***Background.*** Previous Japanese studies of childhood B-cell non-Hodgkin lymphoma (B-NHL) have shown a favorable outcome, though the study size was too small to effectively assess the efficacy and safety of treatment for childhood B-NHL. ***Procedure.*** We performed a nation-wide prospective B-NHL03 study to assess the efficacy and safety of short-pulse intensive chemotherapy for children with B-NHL. They were stratified into four treatment groups according to disease stage, tumor resectability and bone marrow/CNS involvement: Group 1 with all resected stage I/II, Group 2 with non-resected stage I/II, Group 3 with stage III & CNS-negative stage IV, and Group 4 with CNS-positive stage IV & Burkitt leukemia. Treatment duration was 2 courses for Group 1, 4 courses for Group 2, and 6 courses for Groups 3 and 4, respectively. CNS irradiation was omitted in all patients. ***Results.*** The follow-up time ranged from 0.8 to 88 months, with a median of being 45 months. For 321 patients analyzed in this study, overall survival and event-free survival (EFS) at 4 years was 92.7% and 87.4%, respectively. The 4-year EFS according to treatment group were 94% for Group 1 (n = 17), 98% for Group 2 (n = 103), 84% for Group 3 (n = 111), and 78% for Group 4 (n = 90). There was no significant difference in outcome by histology. Therapy-related death occurred in three patients in remission. ***Conclusions.*** Our nationwide large-scale study resulted in a cure rate above 90% with <1% toxic death in childhood B-NHL. Pediatr Blood Cancer 2014;61:1215–1221.


**Key words:** B-NHL03; childhood; JPLSG; non-Hodgkin lymphoma

## INTRODUCTION

Childhood B-cell non-Hodgkin Lymphoma (B-NHL) consists mainly of two histological subtypes, namely Burkitt lymphoma (BL), which includes Burkitt leukemia (B-ALL), and diffuse large B-cell lymphoma (DLBCL). The cure rate of childhood BL has been markedly improved over the past 30 years, and long-term event-free survival (EFS) of patients has reached to approximately 90%. This is largely due to prospective studies of European and North American groups that developed a short intensive chemotherapy regimen, including a high-dose methotrexate (HDMTX), an intermediate dose of cyclophosphamide (CPA), and anthracyclines [1–6]. Although DLBCL is a distinct disease entity from BL, the treatment is the same as that for patients with Burkitt histology, and excellent outcome has been reported [1–6]. Previously most clinical experiences of childhood B-NHL were reported by European and North American study groups, and there were few data on Japanese or Asian patients with B-NHL. In the1990s, we conducted group-wide trials for childhood B-NHL [7–10]: Horibe et al. showed a 4-year EFS with 70% for 57 patients (BL 31, B-ALL 17, DLBCL 9) [8], Kikuchi et al. showed a 6-year EFS with 82% for 91 patients (BL 45, B-ALL 9, DLBCL 26, others 11) [10], and Tsurusawa et al. showed a 7-year EFS with 93% for 30 patients with DLBCL [9]. In addition, Lee et al. has recently shown a 5-year EFS with 95% for 61 patients (BL 46, DLBCL 15) [11]. However, the treatment duration of these studies was relatively long and the number of patients was small compared to the European and North American studies [1–6].

Here, we report on the results of the nation-wide large prospective study for children with B-NHL. The primary object was to evaluate the efficacy and safety of short-pulse intensive chemotherapy regimen designed by the Japanese Pediatric Leukemia/Lymphoma Study Group (JPLSG).


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## PATIENTS AND METHODS

### Study Design and Diagnostic Criteria

The B-NHL03 study was a prospective nonrandomized trial that investigated the efficacy and safety of short-pulse intensive chemotherapy in childhood B-NHL. The chief aim was to improve the outcomes of patients enrolled in the B-NHL03 study to the level of those of European and North American studies.

Additional Supporting Information may be found in the online version of this article.

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Conflict of interest: Nothing to declare.

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The diagnosis of B-NHL was based on histopathology, immunocytochemistry, and cytogenetics. All histopathological specimens were first classified by the institutional pathologist and finally each of them were reviewed by a group of seven pathologists of a central pathological review committee according to WHO classification, that is, BL or Burkitt-like lymphoma (BLL), DLBCL, mediastinal large B-cell lymphoma (MLBCL), and mature B-cell neoplasm, NOS (not otherwise specified) [12]. A mature B-cell phenotype was primarily defined as positive for C20 and/(or) CD79a and negative for CD3 and terminal deoxynucleotidyl transferase. When an immunophenotype study was not available, specific translocations t(8;14)(q24;q32), t(2;8)(p11;q24), t(8;22)(q24;q11) at cytogenetic analysis were included. CNS involvement was diagnosed by the presence of one or more of the following: any blasts with FAB L3 morphology in CSF, isolated intracerebral mass, or intra-spinal extension. The clinical stage was defined by Murphy's classification [13].

## Treatments

The treatment outline is shown in Figure 1 and chemotherapy regimens are shown in Table I. They were stratified into four treatment groups according to disease stage, tumor resectability and bone marrow/CNS involvement: Group 1 with all resected stage I/II, Group 2 with non-resected stage I/II, Group 3 with stage III & CNS-negative stage IV, and Group 4 with CNS-positive stage IV & B-ALL. All groups except Group 1 received a pre-phase therapy of prednisolone (PSL), vincristine (VCR), CPA and it (intrathecal) MTX to reduce tumor volume. As shown in Figure 1, Group 1 received two courses (1A × 2), Group 2 received 4 courses (2A × 2 + 2B × 2), Group 3 received 6 courses (3A × 4 + 3B × 2), and Group 4 received 6 courses (4A1 × 2 + 4A2 × 2 + 4B × 2), respectively. No patients received prophylactic cranial irradiation. Patients with CNS involvements received HDMTX (5 g/m$^2$) plus an extended it regimen (14 times), but no therapeutic cranial irradiation. The schedule of HDMTX administration was identical

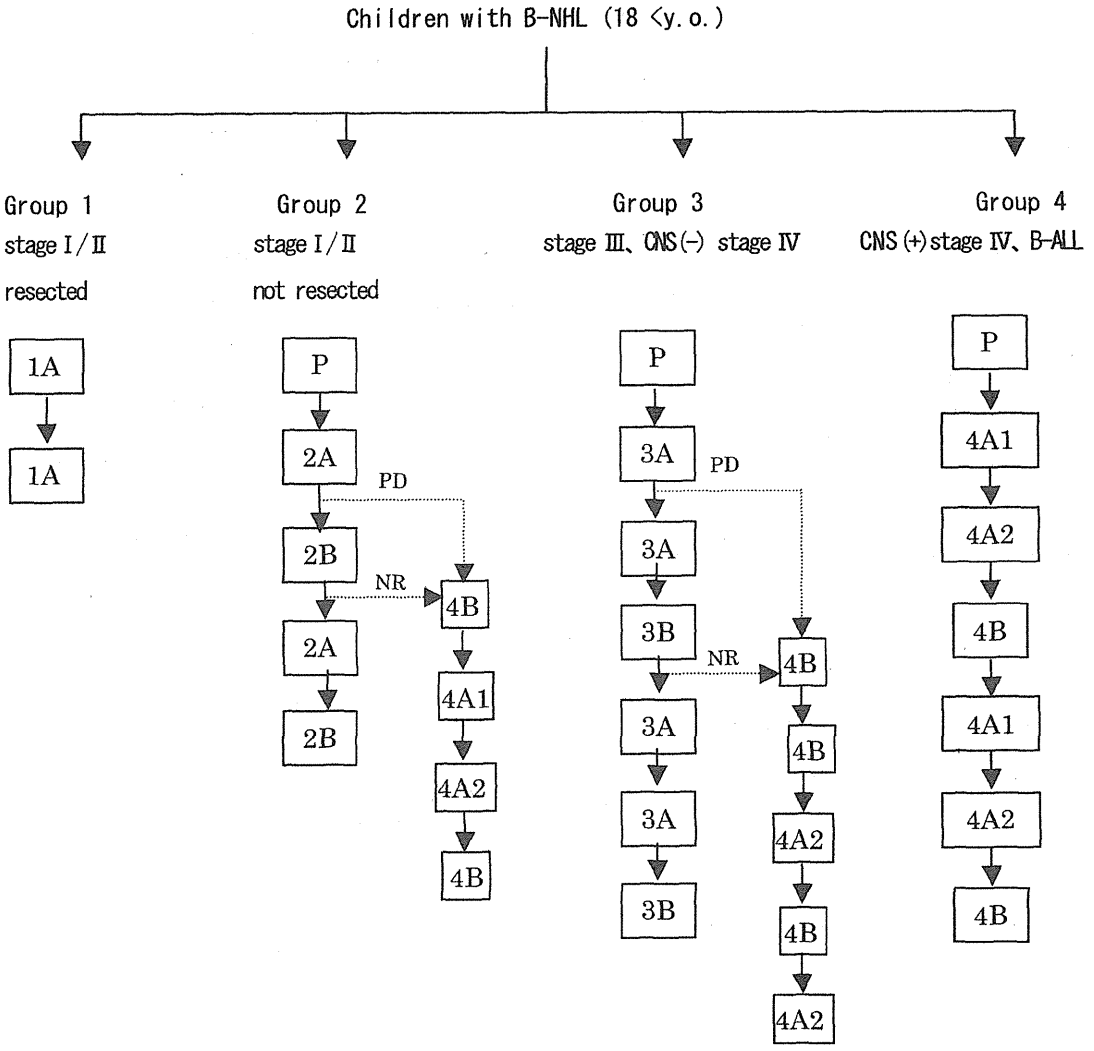


**Fig. 1.** Treatment framework of the B-NHL03 study. Patients were stratified into four treatment groups according to disease stage, tumor resectability, and BM/CNS involvement. All groups except Group 1 received pre-phase therapy. Group 1 received two courses of chemotherapy, Group 2 received 4 courses, Groups 3 and 4 received 6 courses, respectively. When patients in Group 2 or 3 did not achieve CR or CRu during the first 2 or 3 courses, they received salvage therapy consisting of 4B and 4A1/2 courses.

**TABLE I. B-NHL03 Treatment Schedules**

| Regimen | Administration | Daily dose | Days |
|---|---|---|---|
| Pre-phase | | | |
| Prednisolone | Orally | 30 mg and 60 mg/m$^2$ | Days 1–3 and 4–7 |
| Vincristine | IV | 1 mg/m$^2$ | Day 3 |
| Cyclophosphamide | IV | 150 mg/m$^2$ | Days 4–6 |
| Methotrexate | TIT | 12 mg/m$^2$ | Day 1, (4)[a] |
| Hydrocortisone | TIT | 25 mg/m$^2$ | Day 1, (4)[a] |
| Cytarabine | TIT | 30 mg/m$^2$ | Day (4)[a] |
| Regimen 1A | | | |
| Prednisolone | Orally | 60 mg/m$^2$ | Days 1–5 |
| Methotrexate | IV | 1 g/m$^2$ | Day 1 |
| Vincristine | IV | 1.5 mg/m$^2$ | Day 2 |
| Cyclophosphamide | IV | 250 g/m$^2$ × 2 | Days 2–4 |
| THP-adriamycin | IV | 30 mg/m$^2$ | Days 3, 4 |
| Methotrexate | DIT | 12 mg/m$^2$ | Day 1 |
| Hydrocortisone | DIT | 25 mg/m$^2$ | Day 1 |
| Regimen 2A | | | |
| Same as 1A except for dexamethasone | Orally | 10 mg/m$^2$ | Days 1–7 |
| Methotrexate | IV 24 hours with LV rescue | 3 g/m$^2$ | Day 1 |
| Regimen 3A | | | |
| Same as 2A except for *t.i.t* at day 1 | | | |
| Regimen 4A1 | | | |
| Same as 3A except for methotrexate | IV 24 hours with LV rescue | 5 g/m$^2$ | Day 1 |
| Methotrexate | TIT | 12 mg/m$^2$ | Day 1, (5),[a] 8 |
| Hydrocortisone | TIT | 25 mg/m$^2$ | Day 1, (5),[a] 8 |
| Cytarabine | TIT | 30 mg/m$^2$ | Day 1, (5),[a] 8 |
| Regimen 4A2 | | | |
| Same as 4A1 except for cyclophosphamide | IV | 1 g/m$^2$ | Days 4, 5 |
| Regimen 2B | | | |
| Methotrexate | IV 6 hours | 500 mg/m$^2$ | Day 1 |
| Cytarabine | cIV | 150 mg/m$^2$ | Days 1–5 |
| Methotrexate | DIT | 12 mg/m$^2$ | Day 1 |
| Hydrocortisone | DIT | 25 mg/m$^2$ | Day 1 |
| Regimen 3B | | | |
| Same as 2B except for TIT at day 1, and cytarabine | cIV | 150 mg/m$^2$ | Days 1–6 |
| Etoposide | IV | 100 mg/m$^2$ × 2 | Days 3–5 |
| Regimen 4B | | | |
| Same as 3B except for without methotrexate, DIT at day 1 and TIT at day 8, and dexamethasone | Orally | 10 mg/m$^2$ | Days 1–7 |
| Cytarabine | IV | 2 g/m$^2$ × 2 | Days 2–4 |
| Etoposide | IV | 150 mg/m$^2$ | Days 2–5 |
| Vincristine | IV | 1.5 mg/m$^2$ | Day 1 |

LV, leucovorin; IV, intravenous; cIV, continuous intravenous; DIT, double intrathecal; TIT, triple intrathecal. [a]For CNS positive patients.

to that of the B-NHL960 study [9]: HDMTX was administered for the first 24 hours, and 12 hours later, leucovorin (LV) 15 mg/m$^2$ was given orally every 6 hours, for a total of seven doses [9]. Blood MTX concentration was measured 24, 48, and 72 hours after the MTX administration. When patients showed delayed MTX clearance ($\geqq$0.2 μM after 72 hours), LV rescue was continued until MTX concentration level decreased to less than 0.2 μM.

Induction failure (IF) was defined as patients who did not achieve complete remission (CR) or unconfirmed remission (CRu) until the last evaluation time (before the second course of 2A in Group 2, before the third course of 3A in Group 3, before the second course of 4A1 in Group 4). When patients in Group 2 or 3 were evaluated to have progressive disease or no response during the first 2 or 3 courses, they received salvage therapy consisting of regimens 4B and 4A1/2. The cumulative dose of cytotoxic drugs for treatment groups was as follows: CPA 3 g/m$^2$, THP 120 mg/m$^2$ for Group 1; CPA 3.45 g/m$^2$, THP 120 mg/m$^2$ for Group2; CPA 6.45 g/m$^2$, THP 240 mg/m$^2$, VP16 0.6 g/m$^2$ for Group 3; CPA 7.45 g/m$^2$, THP 240 mg/m$^2$, VP16 1.2 g/m$^2$ for Group 4.

## Statistical Analysis

Final statistical analyses were performed based on data obtained in June 2012. Overall survival (OS) was defined as the time between diagnosis and death from any causes, and EFS was defined as the time to first events defined as an occurrence of induction failure, relapse at any site, death from any causes, or second malignant neoplasm. For patients who did not experience an event, EFS was defined as the time to the last follow-up. Survival curves were prepared using the Kaplan–Meier method and standard errors (SEs) with the Greenwood formula. The significance of differences in survival outcomes was determined by means of the log-rank test.