Pediatric Acute Leukemia: The Effect of Prognostic Factors on Clinical Outcomes at Phramongkutklao Hospital, Bangkok, Thailand

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Background: *Leukemia is the most common malignancy in children. Multiple prognostic factors have been used in order to assist the clinician to decide appropriate risk-adjusted treatment for each patient; the current clinical outcomes of those patients have been significantly improved over the past decades.*

Objective: *The purpose of this study was to examine survival outcome in children who were diagnosed with acute leukemia and treated in the Department of Pediatrics, Phramongkutklao Hospital during January 1, 2000 and July 31, 2013.*

Material and Method: *The authors retrospectively reviewed the patients who were diagnosed with acute leukemia and treated at Phramongkutklao Hospital. Their clinical data were collected and analyzed based on clinical features including age, initial WBC count at diagnosis, sex, immunophenotype and cytogenetic abnormalities.*

Results: *Total 152 patients with acute leukemia, 123 patients were diagnosed with acute lymphoblastic leukemia (ALL) and 29 patients were diagnosed with acute myeloid leukemia (AML). The 5-year survival rates of ALL and AML patients were 72.63% and 30.30%, respectively. In addition, we found a correlation between the ALL patients' clinical outcomes and several prognostic factors including initial white blood cell count, CNS status at diagnosis and ploidy. However, there was no correlation between those factors and clinical outcomes in AML patients.*

Conclusion: *Our treatment outcomes on patients with acute leukemia were similar to the reports from other countries. The several prognostic factors especially initial WBC at diagnosis can assist the clinician to select appropriate treatment option for each patient.*

Keywords: *Acute leukemia in children, Prognostic factors, Survival outcomes*

J Med Assoc Thai 2014; 97 (Suppl. 2): S188-S195
Full text. e-Journal: *http://www.jmatonline.com*

In Thailand, the incidence of malignant neoplasm in children <15 years of age was reported to be approximately 1,000 cases/year[1,2]. Given the limited data obtained from small numbers of tertiary-care hospital, these numbers might be underestimated. Among those cases, leukemia was the most common type of cancer and accounted for 50.9% of all childhood cancers[2]. Acute lymphoblastic leukemia (ALL) was reported to be the most common type of leukemia accounted for 72.4% of all childhood leukemia, followed by acute myeloid leukemia (AML) (23.1%), chronic myeloid leukemia (CML) (3.6%) and other specified leukemia (0.9%), which was similar to the reports from other countries worldwide[3]. The survival of childhood leukemia was generally dependent on the specific type of disease (ALL vs. AML vs. CML). According to the report from Wiangnon et al, 5-year survival of patients with ALL was 64.9% (61.7-67.9%) compared to the survival of patients with AML (35.5%; 30.2-40.8%) and CML (50.6%; 35.7-63.8%)[2].

The prognosis of children with leukemia has improved remarkably during the past decades especially in children with ALL. The main reasons for this excellent outcome are intensive multi-agent chemotherapy and the use of risk-adapted therapy according to the prognostic factors. The treatment modalities[4] includes systemic chemotherapy and intrathecal chemotherapy, which reduced the frequency of overt manifestations

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of acute leukemia in the central nervous system to less than 5% for standard risk patients. The common systemic chemotherapy in childhood ALL includes vincristine, prednisone, oral 6-mercap-topurine, L-asparaginase, adriamycin, and cytarabine with anthracycline in AML. The risk classification effects on duration of treatment and central nervous system (CNS) prophylaxis that include intrathecal chemotherapy. The higher risk classification, the longer duration for chemotherapy will be given and plus more frequently given of intrathecal chemotherapy. According to standard treatment of acute leukemia in children, patients are treated with low, intermediate, high risk protocol, depending on their standard clinical and laboratory prognostic factors such as cytogenetic, flow cytomety etc. In children with ALL, multiple prognostic factors have been characterized including age at the diagnosis, initial white blood cell number, immunophenotypes, cytogenetic abnormalities, central nervous system (CNS) involvement, early response to induction therapy and minimal residual disease (MRD). These prognostic factors are now being used to stratify children with ALL into different risk groups (low risk vs. standard risk vs. high risk), which require different risk-adapted therapies. In children with AML, cytogenetic abnormalities play an important role in predicting the outcome.

Here, the aim of the presence study was to review our children who were diagnosed with acute leukemia and treated at Phramongkutklao Hospital from the time of diagnosis, to evaluate its contribution as prognostic factors by correlated the results with clinical outcome.

The association between the characterized prognostic factors and clinical outcome was also intensively analyzed.

Material and Method

The authors retrospectively reviewed our experience regarding one hundred and fifty-two patients who were diagnosed with acute leukemia and underwent chemotherapy containing treatment protocols at the Division of Hematology/Oncology, Department of Pediatrics, Phramongkutklao Hospital between January 1, 2000 and July 31, 2013. The authors analyzed outcome based on clinical features including age, initial WBC count at diagnosis, sex, immunophenotype and cytogenetic abnormalities. The study was performed in accordance with the declaration of Helsinki, and was approved by the local ethics committee at Pharmongkutklao Hospital.

Statistical analysis

The probability of overall survival was estimated by the Kaplan-Meier method and was compared between groups by the log-rank test. Overall survival (OS) was measured from the day of first diagnosis of acute leukemia to the day of death. Cumulative incidence of relapse (CIR) was estimated after adjusting for competing risk of death. Cox regression analysis was used to identify factors significantly associated clinical outcome. Categorical variables were presented with frequency and percentage. Continuous variables were expressed as the mean and standard deviation (SD) or median (range). The STATA/MP 12 was used for the statistical analysis. A *p*-value of less than 0.05 was considered statistically significant.

Table 1. Patient characteristics with acute lymphoblastic leukemia

	Total (n = 123) (%)
Age at diagnosis (years)	
Median (range)	10.67 (0.44-21.75)
Gender	
Female	42 (34.15)
Male	81 (65.85)
Immunophenotypes	
B-lineage	99 (80.49)
T-lineage	20 (16.26)
Unclassified	4 (3.25)
Initial WBC count (cells/mm^3)	
Median (range)	9,000 (4,040-919,000)
Risk groups	
Low risk	66 (53.66)
High risk	53 (43.09)
Unclassified	4 (3.25)
CNS status	
*CNS 1	118 (95.93)
+CNS 2	2 (1.63)
#CNS 3	3 (2.44)
Disease status	
Remission	95 (77.24)
Relapse	28 (22.76)
Causes of death	
Relapse	25 (83.33)
Complications	5 (16.67)

*+# Identification of blast cells on cytocentrifuge examination.
CNS involvement in leukemia is classified as follows:
*CNS1, no blasts on cytocentrifuge slide
+CNS2 <5 WBCs/mm^3, blasts on cytocentrifuge slide
#CNS3 >5 WBCs/mm^3, blasts on cytocentrifuge slide

Table 2. Patient characteristics with acute myeloid leukemia

	Total (n = 29) (%)
Age at diagnosis (years)	
Mean	7.68 (0.65-18.44)
Gender	
Female	15 (51.72)
Male	14 (48.28)
Subtypes	
M1	6 (20.69)
M2	9 (31.03)
M5	8 (27.59)
M6	1 (3.45)
Unclassified	5 (17.24)
Initial WBC count (cells/mm^3)	
Median (range)	12,900 (800-476,000)
Disease status	
Remission	15 (51.72)
Relapse/refractory	14 (48.28)
Causes of death	
Relapse/refractory	14 (93.33)
Complications	1 (6.67)

M1 = Acute myeloblastic leukemia without maturation; morphologically indistinguishable from L2 Morphology
M2 = Acute myeloblastic leukemia with differentiation
M5 = Acute monocytic leukemia containing poorly differentiated and/or well-differentiated monocytoid cells
M6 = Acute erythrocytic leukemia

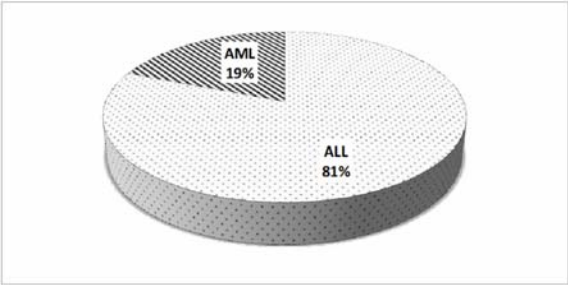

Fig. 1 Distribution of acute leukemia based on leukemia type (acute lymphoblastic leukemia vs. acute myeloid leukemia).

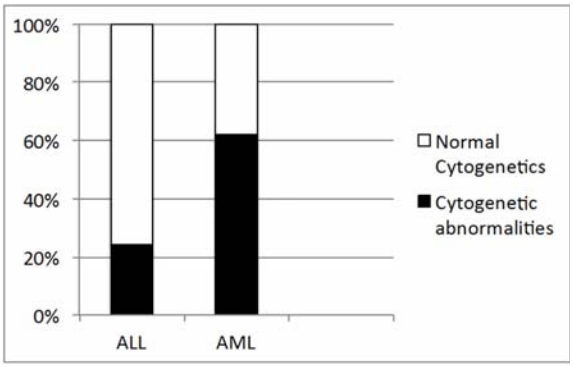

Fig. 2 Frequency of cytogenetic abnormalities found in acute leukemia.

Results

Patient characteristics

Patients' characteristics are summarized in Table 1 and Table 2. Among the patients who were diagnosed with acute leukemia and treated at Phramongkutklao Hospital, 123 patients were diagnosed with acute lymphoblastic leukemia (ALL), and 29 patients were diagnosed with acute myeloid leukemia (AML) (Fig. 1). The cytogenetic abnormalities were more common in patients with AML (Fig. 2).

Among 123 patients with ALL, the mean and median of their age at diagnosis were at 10.67 years with the range between 0.44-21.75 years. Male was more prominent than female. Eighty percent of the patients with ALL were sub-classified as B-lineage leukemia, 16 percent of the patients were sub-classified as T-lineage leukemia and the rest of the patients were sub-classified as unclassified type since all of those patients were diagnosed with ALL during the era when immunophenotype was not available. The mean of patients' initial white blood cell count was 68,085.73 cells/mm^3 with the median of 9,000 cells/mm^3 (range 400-919,000 cells/mm^3). Most of the patients were stratified as low-risk and had no central nervous system involvement. Seventy-seven percent of the patients were in remission. Approximately 22% of the patients suffered a relapsed and most of them expired from disease progression.

Among 29 patients with AML, the mean of their age at diagnosis were at 8.30 years with the median of 7.68 years (range 0.65-18.44). The disease was equally distributed between male and female. Most of the patients could be sub-classified according to WHO classification with only 5 patients who had unclassified type. The mean of patients' initial white blood cell count was 73,848.15 cells/mm^3 with the median of 12,900 cells/mm^3 (range 800-476,000 cells/mm^3). Approximately half of the patients were in remission and all of the patients who experienced a relapse of the disease expired.

Survival outcomes

Kaplan-Meier curves were plotted on 123 patients who were diagnosed with ALL and 29 patients who were diagnosed with AML. The 5-year overall survival of those patients with ALL was 72.63% [95%

CI: 62.40-80.50] and the patients with AML was 30.30% [95% CI: 12.04-51.01]. The 5-year event free survival of those patients with ALL was 72.06% [95% CI: 61.27-80.31] and the patients with AML was 46.88% [95% CI: 24.25-66.69] (Fig. 3).

Correlation of prognostic factors and clinical outcomes

Several prognostic factors were analyzed in order to determine whether they were correlated with clinical outcomes (Fig. 4). In patients with ALL, there were no statistical differences between the cell types (T-lineage or B-lineage) and the overall survival (p = 0.338), event free survival (p = 0.206) and cumulative incidence of relapse. However, initial WBC count at diagnosis could possibly be used as prognostic indicator for patient's clinical outcomes given that the

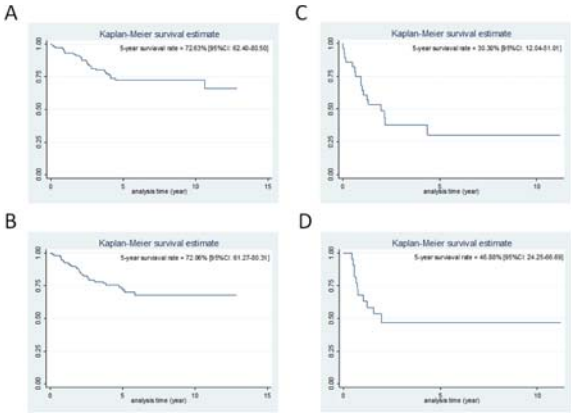

Fig. 3 Overall survival (A and C) and event free survival (B and D) in patients with acute lymphoblastic leukemia (ALL) (A, B) and acute myeloid leukemia (AML) (C, D).

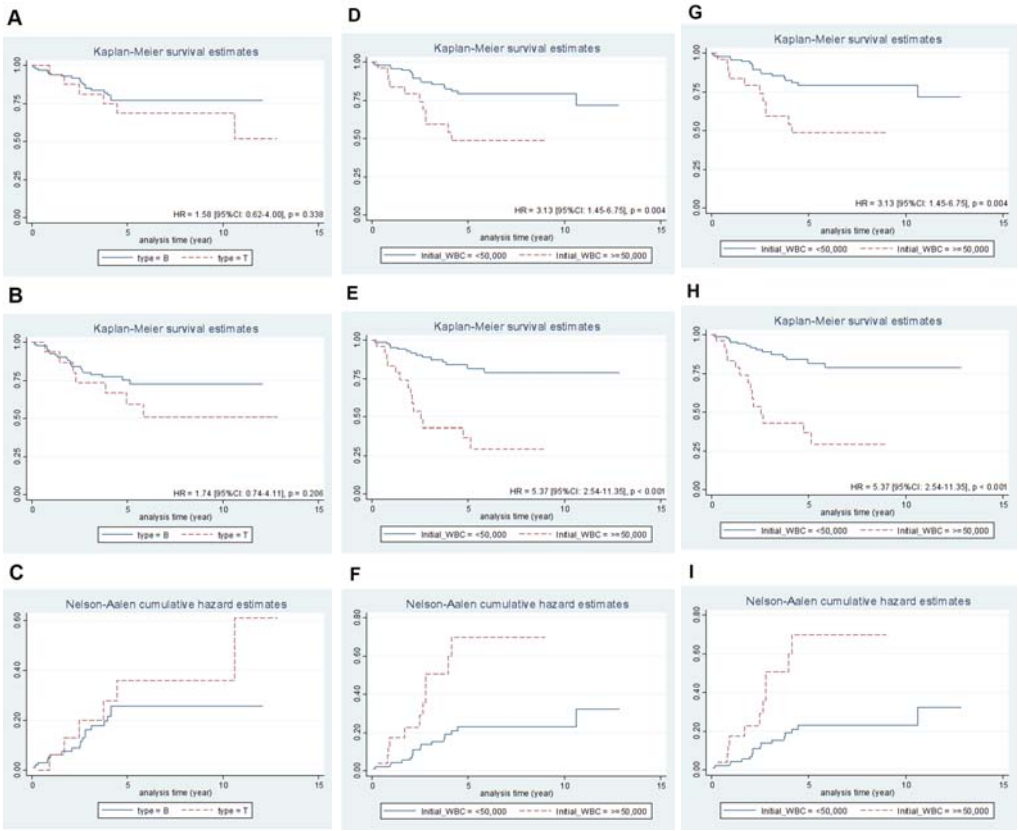

Fig. 4 Overall survival (A, D and G), event free survival (B, E and H) and cumulative incidence of relapse (C, F and I) in patients with acute lymphoblastic leukemia (ALL). The graphs were generated separately on patients who had B-lineage vs. T-lineage ALL (A, B and C), age at diagnosis between 1-9 years vs. more than 10 years (D, E and F), initial white blood cell count ≥50,000 cells/mm^3 vs. <50,000 cells/mm^3 (G, H and I).

patients with ALL who had WBC ≥50,000/mm^3 had significantly worse overall survival (p = 0.004), event free survival (p<0.001) and significantly higher cumulative incidence of relapse than the patients with ALL who had WBC <50,000/mm^3. When we further analyzed the clinical data by dividing those patients according to their cell type origins, interestingly, we found that only the patients with B-lineage ALL who had WBC ≥50,000/mm^3 had significantly worse overall survival (p = 0.001), event free survival (p<0.001) and significantly higher cumulative incidence of relapse than the patients with B-lineage ALL who had WBC <50,000/mm^3. There were no statistical differences of overall survival (p = 0.296), event free survival (p = 0.396) and cumulative incidence of relapse between the patients with T-lineage ALL who had WBC ≥50,000/mm^3 and the patients who had WBC <50,000/mm^3 (Fig. 5). The authors also looked at the patient's age group, and found no statistical difference of overall survival (p = 0.139) between the patients with ALL who were diagnosed between 1 and 9 years of age and those who were diagnosed at more than 10 years of age. However, the patients with ALL who were diagnosed between 1 and 9 years of age had significantly worse event-free survival (p = 0.044) and significantly higher cumulative incidence of relapse than the patients who were diagnosed at more than 10 years of age. The authors did not perform statistical analysis on the patient with ALL who was diagnosed at less than 1 year of age given that there was only one patient and the patient did expire from refractory disease. Other prognostic factors including central nervous system (CNS) status and ploidy were also analyzed. According to our observation, all seven patients with ALL who had hyperdiploidy (>50 chromosomes) were alive. Three patients with ALL and had CNS leukemia (CNS 3), expired. However, there was no statistical analysis performed on these prognostic factors due to small sample sizes. In patients with AML, the authors found no statistical differences of overall survival (p = 0.149), event free survival (p = 0.687) and cumulative incidence of relapse between the patients with AML who had initial WBC count at diagnosis ≥50,000/mm^3 and the patients who had WBC <50,000/mm^3. In addition, there was also no statistical difference of overall survival (p = 0.841), event-free survival (p = 0.371) and cumulative incidence of relapse between the patients with AML who were diagnosed between 1 and 9 years of age and those who were diagnosed at more than 10 years of age (Fig. 6).

The data were also analyzed by multivariate analysis using the Cox proportional hazards model which revealed the independent risk factor for the risk

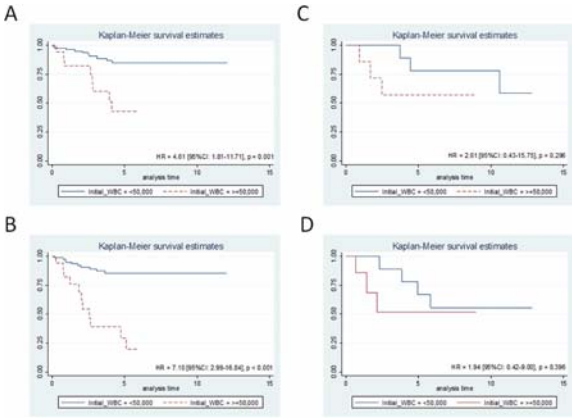

Fig. 5 Overall survival (A, C), event free survival (B, D) in patients with ALL according to their initial white blood cell count. The graphs were generated separately on patients who had B-lineage ALL (A, B) and those who had T-lineage ALL (C, D).

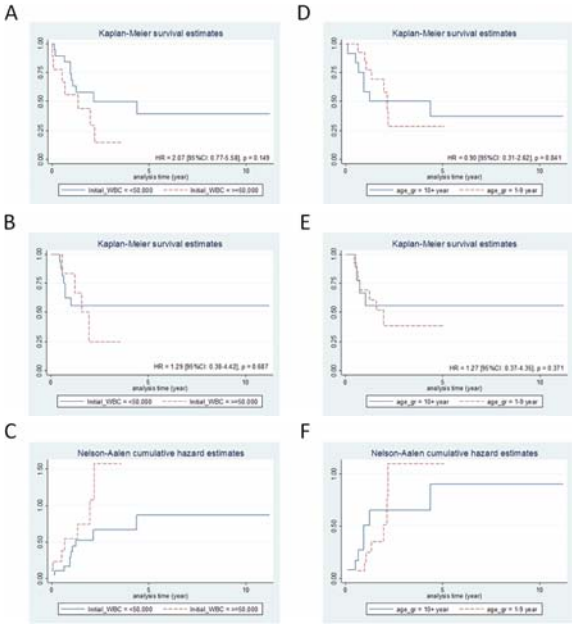

Fig. 6 Overall survival (A, D), event free survival (B, E) and cumulative incidence of relapse (C, F) in patients with acute myeloid leukemia (AML). The graphs were generated separately on patients who had initial white blood cell count ≥50,000 cells/mm^3 vs. <50,000 cells/mm^3 (A, B and C), age at diagnosis between 1-9 years vs. more than 10 years (D, E and F).

Table 3. Multivariate analysis using Cox proportional hazards model

	Overall survival (OS)			Event free survival (EFS)		
	HR	95% CI	*p*-value	HR	95% CI	*p*-value
ALL patients						
T-lineage	1.09	0.37-3.19	0.870	1.25	0.47-3.35	0.656
WBC ≥50,000/mm^3	3.65	1.47-9.04	0.005	4.53	2.01-10.2	<0.001
Age (1-9 years)	2.15	0.84-5.52	0.110	1.54	0.68-3.47	0.302
Male	1.31	0.50-3.48	0.583	0.89	0.38-2.12	0.801
AML patients						
WBC ≥50,000/mm^3	2.54	0.53-12.29	0.246	0.88	0.14-5.55	0.889
Age (1-9 years)	0.61	0.17-2.24	0.454	1.32	0.29-5.99	0.719
Male	1.23	0.33-4.54	0.755	0.67	0.14-3.30	0.624

ALL = acute lymphoblastic leukemia; AML = acute myeloid leukemia

of relapse was only having initial WBC ≥50,000/mm^3 [HR 4.53 (95% CI: 2.01-10.2)]. Other variables including sex, immunophenotype and age group were not associated with the risk of relapse. However, the population of AML patients found initially WBC did not indicate independently risk factors leading to relapse in ALL patients.

Discussion

Leukemia is the most common malignancy in children, representing one-third of all childhood cancers. There is currently an initiative to reduce the mortality gap between pediatric cancer in developed and low-income countries. The clinical outcome of this cancer has been significantly improved over the past decades by the use of risk-adjusted multi-agent chemotherapy and central nervous system (CNS) control (intrathecal chemotherapy administration and/or cranial irradiation). With regard to the risk-adjusted multi-agent chemotherapy, each individual will be stratified upfront after the diagnosis of acute leukemia is confirmed by using multiple prognostic factors including the patients' age at diagnosis, initial white blood cell count, ploidy, CNS status, immunophenotype of leukemia cell and cytogenetic abnormalities. This systematic treatment approach will assist the clinician to deliver more intense and effective treatment to high-risk patients with the aim to improve their survival and to deliver less intense and appropriate treatment to low-risk patients in order to minimize their treatment-related toxicity.

In the present study, the authors retrospectively reviewed and analyzed the clinical data from our pediatric patients who were diagnosed with acute leukemia and treated at Phramongkutklao Hospital. Similar to other countries, our patient population who were diagnosed with acute lymphoblastic leukemia (ALL) was more prominent than those who were diagnosed with acute myeloid leukemia (AML), and the survival outcomes in the patients with ALL were also superior to those in the patients with AML. In patients with ALL, multiple prognostic factors including the patients' age at diagnosis, initial white blood cell count, ploidy, central nervous system status, immunophenotype of leukemic cell and cytogenetic abnormalities were analyzed in order to determine whether they could truly be used to predict our patients' clinical outcomes. As expected, the authors found that the patients' initial white blood cell (WBC) count was significantly associated with the clinical outcomes by which those patients who had initial WBC of ≥50,000 cells/mm^3 will have worse overall, survival, worse event-free survival and higher cumulative incidence of relapse comparing to those with initial WBC of <50,000 cells/mm^3. When we further performed statistical analysis by sub-classified the patients to B-lineage and T-lineage ALL, interestingly, we found that initial high WBC was the worse prognostic factor for only individuals who had B-lineage ALL, but not in T-lineage ALL. The present study showed that 80 percent of the patients with ALL were sub-classified as B-lineage leukemia, 16 percent of the patients were sub-classified as T-lineage leukemia which was very similar to that in European countries and US[5,6].

Regarding the immunophenotype of ALL, we observed no statistical differences of clinical outcomes between the patients with T-lineage ALL and those with B-lineage ALL. This could be explained from those

individuals with T-lineage ALL were stratified as high-risk patients and treated with more intense chemotherapy. Although the sample sizes of our patients who had CNS involvement (CNS3) and our patients who had hyperdiploidy (>50 chromosomes) were low and not be able to statistically analyzed. Our observation revealed that CNS involvement was a good predictive factor for worse prognosis given that all 3 patients with CNS3 expired from disease progression and hyperdiploidy, thus a good predictive factor for good prognosis given that all 7 patients with hyperdiploidy are alive. Patients' cytogenetic data were also collected and analyzed; however, the statistical analysis could not be performed due to the small sample sizes.

At the present, only three reports are available in the medical literature regarding cytogenetic analysis in children with ALL in developing countries. The previous studies provided by Emerenciano M et al[7] from Brazil, Perez-Vera et al[8] from Mexico City, and Chang HH et al[9] from Taiwan were all institutional studies; they described the frequency of the chromosomal abnormalities in ALL patients without making any correlation with clinical risk factors. It implied that the prevalence of cytogenetic abnormalities in ALL in developing countries varied and needed more sample sizes to detect the difference on clinical outcome.

Interestingly, the authors found that the older patients did well and had better clinical outcomes than the younger patients. This might be from other factors. Hunger SP et al[10] showed that older children with ALL should be referred to pediatric treatment centers. By contrast, a Finnish study[11] reported similar outcomes for pediatric and adult protocols, and suggested that both protocols were fairly similar.

In patients with AML, the authors did not observe the statistical correlation between the patients' clinical outcomes and the prognostic factors including the patients' age at diagnosis and the initial WBC numbers. This was due to the small sample size of our AML patient.

In summary, the overall clinical outcomes of the patients who were diagnosed with acute leukemia in our institution were similar to other countries. Several prognostic factors were statistically correlated to patients' clinical outcomes and can assist the clinician to select the appropriate risk-adjusted treatment.

Acknowledgement

This study was supported by funding from the Phramongkutklao Hospital Foundation.

Author contributions

PR, SK, CM, CT participated in study design, collection of data, statistical analysis and manuscript writing. All the authors participated in draft revisions and approval of the final manuscript.

Potential conflicts of interest

None.

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ปัจจัยสำคัญในการพยากรณ์โรคต่อผลการรักษาโรคมะเร็งเม็ดเลือดขาวในเด็ก ณ โรงพยาบาลพระมงกุฎเกล้า

ปิยะ รุจกิจยานนท์, ศุภธิดา แก้วอินแสง, ชาลินี มนต์เสรีนุสรณ์, ชาญชัย ไตรวารี

ภูมิหลัง: *มะเร็งเม็ดเลือดขาวเป็นโรคมะเร็งที่พบได้บ่อยที่สุดในเด็ก ปัจจัยที่สำคัญในการพยากรณ์โรคของมะเร็งเม็ดเลือดขาวในเด็กมีหลากหลาย และมีความจำเป็นอย่างยิ่งที่จะต้องทราบอย่างแน่ชัด เนื่องจากเป็นส่วนสำคัญต่อการพิจารณาการรักษาซึ่งแตกต่างกันออกไป โดยการรักษาในยุคปัจจุบันประสบความสำเร็จมากขึ้นตามลำดับ*

วัตถุประสงค์: *เพื่อศึกษาอัตราการรอดชีวิตในผู้ป่วยเด็กโรคมะเร็งเม็ดเลือดขาวที่ได้รับการวินิจฉัยและรักษา ที่กองกุมารเวชกรรม โรงพยาบาลพระมงกุฎเกล้า ในช่วงระยะเวลาตั้งแต่วันที่ 1 มกราคม พ.ศ. 2543 ถึง วันที่ 31 กรกฎาคม พ.ศ. 2556*

วัสดุและวิธีการ: *เป็นการศึกษาแบบย้อนกลับ โดยอาศัยการทบทวนจากเวชระเบียนของผู้ป่วยเด็กโรคมะเร็งเม็ดเลือดขาว ที่ได้รับการวินิจฉัยและรักษาที่กองกุมารเวชกรรม โรงพยาบาลพระมงกุฎเกล้า โดยมีการรวบรวมและวิเคราะห์ เปรียบเทียบจากลักษณะทั่วไปของผู้ป่วย ได้แก่ อายุ เพศ ระดับเม็ดเลือดขาวตั้งต้นที่วินิจฉัยหรือแรกรับการรักษา การย้อมติดสีของเซลล์มะเร็งและข้อมูลพื้นฐานทางพันธุศาสตร์ของเซลล์มะเร็ง*

ผลการศึกษา: *ผู้ป่วยเด็กโรคมะเร็งเม็ดเลือดขาวจำนวนทั้งสิ้น 152 ราย เป็นโรคมะเร็งเม็ดเลือดขาว ลิมโฟบลาสต์ชนิดเฉียบพลัน 123 ราย และโรคมะเร็งเม็ดเลือดขาวมัยอีโลบลาสต์ชนิดเฉียบพลัน 29 ราย อัตราการรอดชีวิตที่ 5 ปีของโรคมะเร็งเม็ดเลือดขาวลิมโฟบลาสต์ชนิดเฉียบพลันเป็น 72.63% และโรคมะเร็งเม็ดเลือดขาวมัยอีโลบลาสต์ชนิดเฉียบพลันเป็น 30.3% ตามลำดับ และพบว่าระดับเม็ดเลือดขาวตั้งต้นที่วินิจฉัยหรือแรกรับการรักษา การพบรอยโรคที่น้ำไขสันหลัง และจำนวนของโครโมโซมของเซลล์มะเร็ง มีความเกี่ยวข้อง อย่างมีนัยสำคัญต่อการพยากรณ์โรคมะเร็งเม็ดเลือดขาวลิมโฟบลาสต์ชนิดเฉียบพลัน แต่ไม่พบความเกี่ยวข้องดังกล่าวในโรคมะเร็งเม็ดเลือดขาวมัยอีโลบลาสต์ชนิดเฉียบพลัน*

สรุป: *อัตราการรอดชีวิตในโรคมะเร็งเม็ดเลือดขาวในเด็กที่กองกุมารเวชกรรม โรงพยาบาลพระมงกุฎเกล้า ใกล้เคียงกับประเทศที่พัฒนาแล้วอื่น ๆ และปัจจัยที่มีผลกับการพยากรณ์โรค โดยเฉพาะอย่างยิ่งระดับเม็ดเลือดขาวตั้งต้นที่วินิจฉัยหรือแรกรับการรักษาสามารถใช้เป็นแนวทางให้กับแพทย์ผู้รักษา เพื่อจะได้มาซึ่งการรักษาที่เหมาะสมและเป็นประโยชน์สูงสุดกับผู้ป่วยต่อไป*