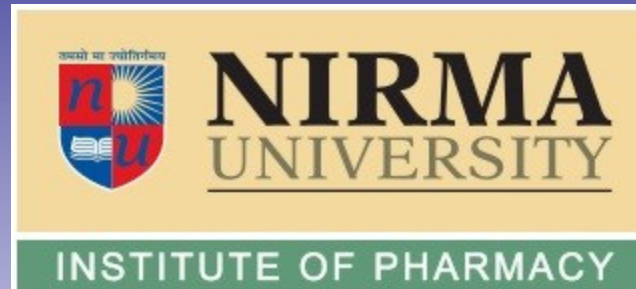


CORRELATION BETWEEN CLINICAL PRESENTATION AND TREATMENT PROTOCOL ON THE OUTCOME OF ACUTE LYMPHOBLASTIC LEUKEMIA AT A TERTIARY CARE CENTRE



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ABSTRACT

Acute Lymphoblastic Leukemia (ALL) is a type of blood cancer that starts from white blood cells in the bone marrow. The objective of present study was to investigate the epidemiological, clinical and prognostic features and the treatment characteristics in patients with acute lymphoblastic leukaemia along with their relationship with event free survival and overall survival. A retrospective, single-centric study involving ALL patients from December 2012 to April 2013 was carried out at the Hemato-Oncology Clinic, Vedanta Institute of Medical Sciences, Ahmedabad, India. Data were recorded for different parameters like complete Remission (CR), Overall Survival (OS), Event Free Survival (EFS), Hb, WBC, Platelet, SGPT and immunophenotype. A total of 142 cases were recorded, which included 101 male patients and 41 female patients. Most patients (63%) had Pre-B types. CR was 96.62%, 97.75% OS and 62.22% EFS in patients of BFM-90 protocol whereas CR 83.63%, 92.72% OS and 56.12% EFS was observed in patients of MCP-841 protocol. Most of the patients (62%) were showing low haemoglobin level (below 10 g/dL), 70% were having low WBC count (< 20,000 /cmm), 67% were having low platelet count (< 200 × 10⁻³/cmm) and 55% were having normal SGPT level (5-40). From the data we conclude that CR, OS, EFS rates achieved represents a significant improvement in ALL patients. Age, Hb, WBC and platelet define the risk group suggesting the prognostic features for ALL patients in India. Complete Remission achieved in the BFM-90 protocol was higher compared to the MCP-841 protocol.

OBJECTIVES:

The prognosis of childhood ALL in the developing world remains poor due to a multitude of adverse clinical and social factors, the most prominent among these being the lack of resources available to both patients and health care professionals. Thus, in order to improve the survival of patients with ALL in developing countries, it is important to conduct research into the biology, response to treatment and prognostic factors in the developing countries themselves. Keeping these insights, we designed a single centric retrospective study the with following aim and objective:

- ⇒ To investigate the epidemiological, clinical, prognostic features and treatment characteristics in patients with acute lymphoblastic leukaemia.
- ⇒ To determine event free survival and overall survival.
- ⇒ To correlate immunophenotyping with overall survival and event free survival.
- ⇒ To determine cost effectiveness of the two treatment protocol (BFM-90 protocol and MCP- 841).

STUDY METHODOLOGY

The study included 142 patients, first seen between 2006 and 2012 at the Hemato Oncology Clinic Vedanta Institute of Medical Science, Ahmedabad. The diagnosis of ALL was based on examination of Bone marrow aspiration and biopsy. Patients were analysed for Hb concentration, platelet count, WBC count, sex, age, mediastinum involvement, lymphadenomegaly, spleenomegaly, hepatomegaly, proportion of blast cells in the marrow. Patients were treated as per BFM-90 or MCP-841 as per Principle Investigator discretion. From the data sheet OS and EFS were also analysed. The study protocol was approved by Ethics Committee of CIMS, Ahmedabad. Descriptive clinical data were expressed in percentage.

RESULTS

A total of 142 cases were recorded including 101male patients and 41 female patients. Among them 58% patients were in age group of 2-18 years. 25% patients were in age group 18-40 years. Most patients had (63%) Pre-B types. However, 20% patients were having Early Pre-B type, 3% B mature and 13% T-ALL immunophenotype. CR was achieved 86 (96.62%), 87 (97.75%) OS, 62.22% EFS in patients of BFM-90 protocol and CR 46 (83.63%), 51 (92.72%) OS, 56.12% EFS in patients of MCP-841 protocol. There were 5 deaths due to infection and 1 death due to seizure. Most of the patients (62%) were showing low haemoglobin level (below 10 g/dL), 70% were having low WBC count (<20,000/cmm), 67% were having low platelet count (<200 × 10⁻³ /cmm), 55% were having normal SGPT level (5-40).

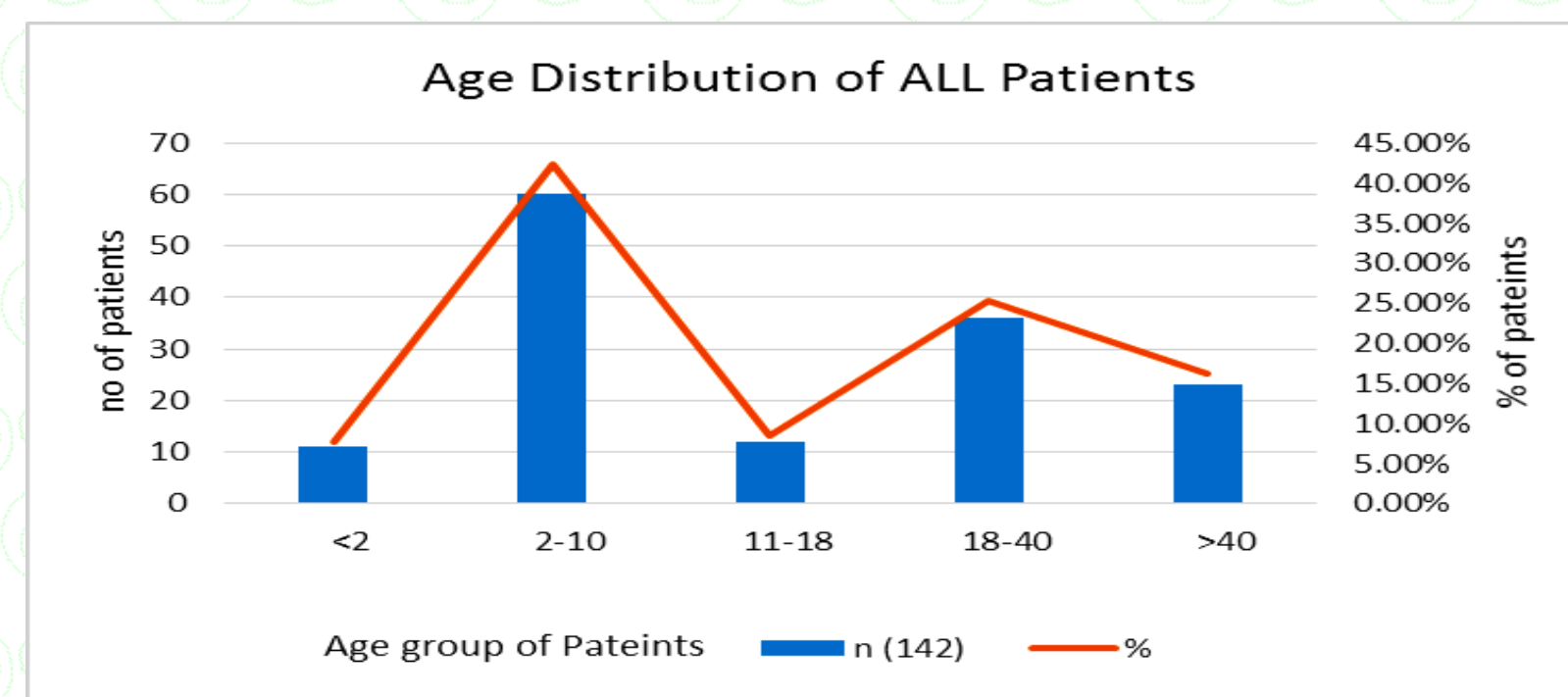


Figure 1: Age Distribution of ALL Patients

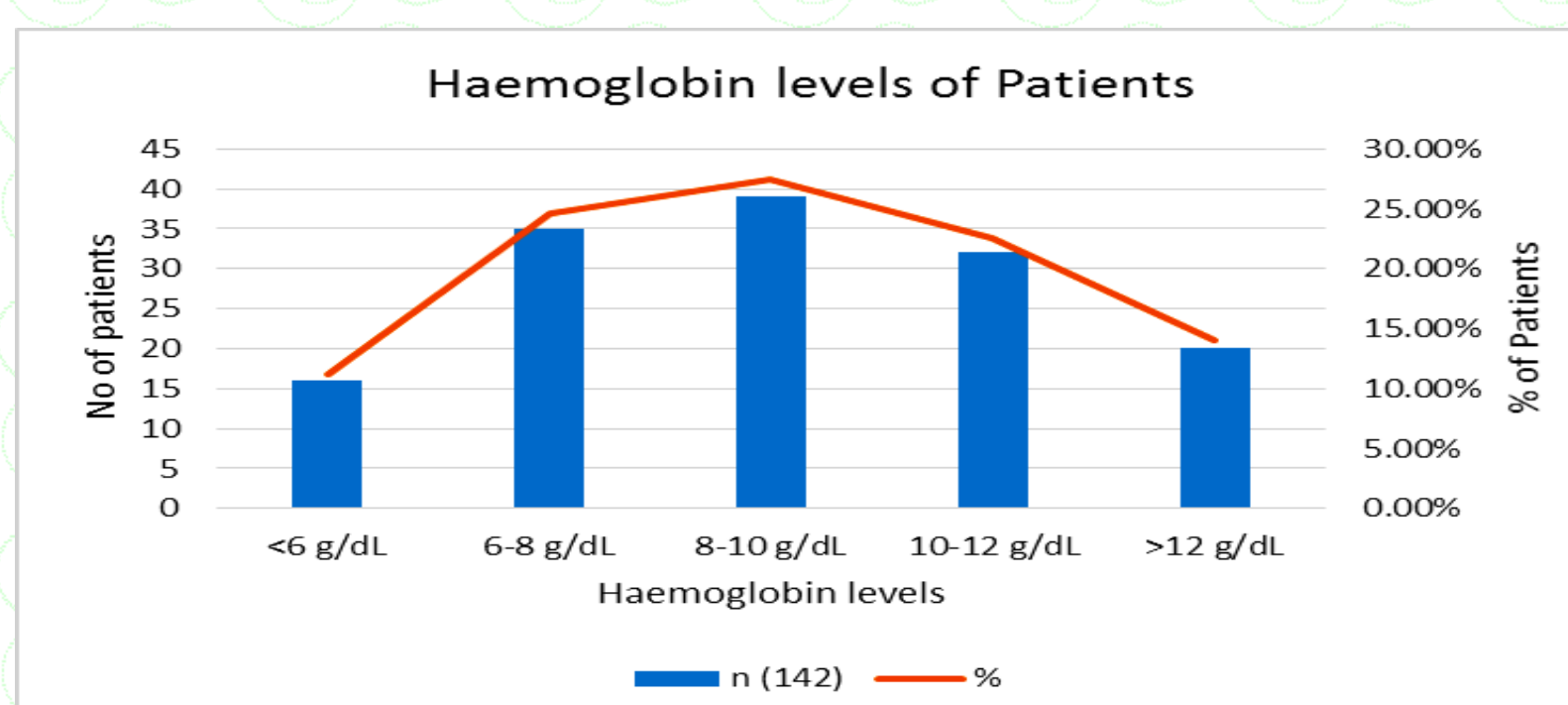


Figure 2: Baseline Haemoglobin Level of ALL Patients

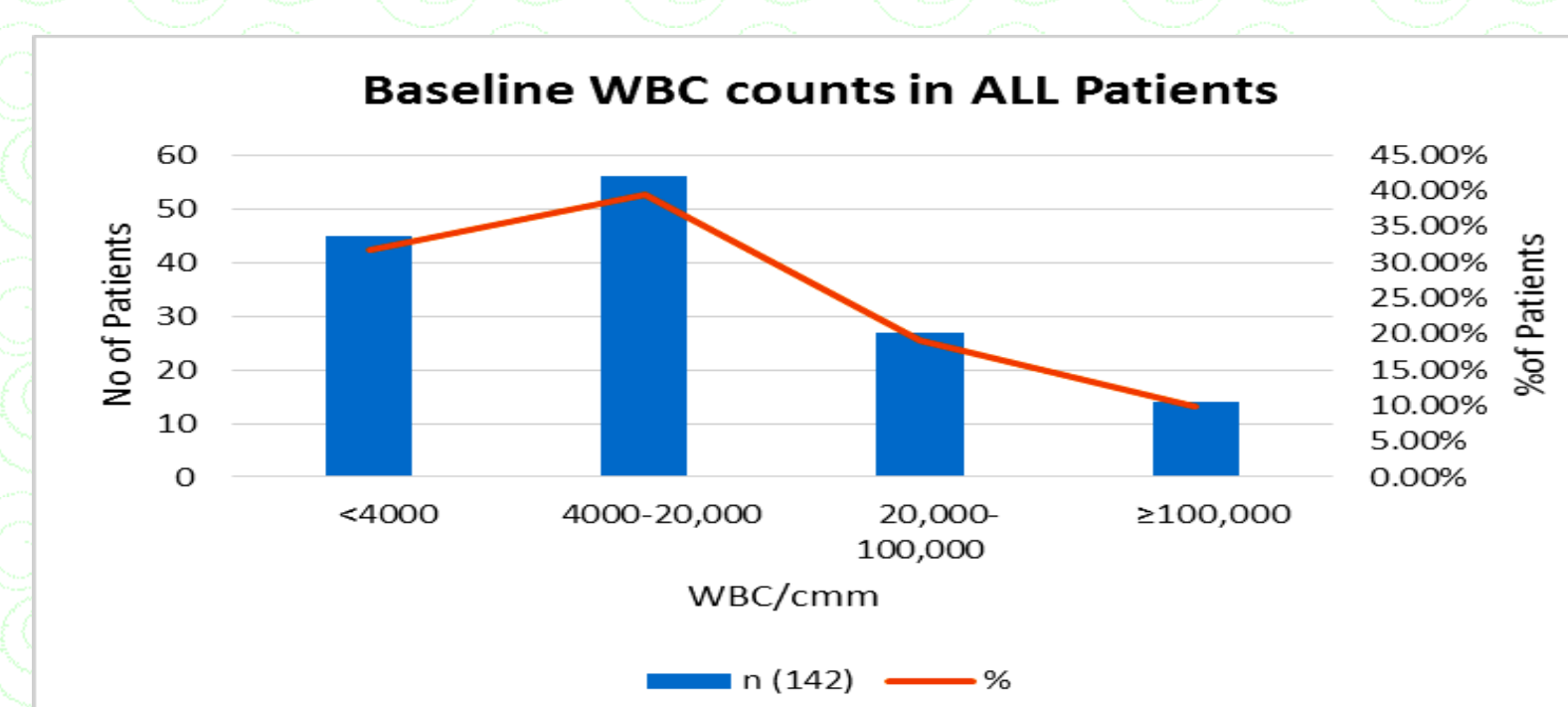


Figure 3: Baseline WBC counts in ALL Patients

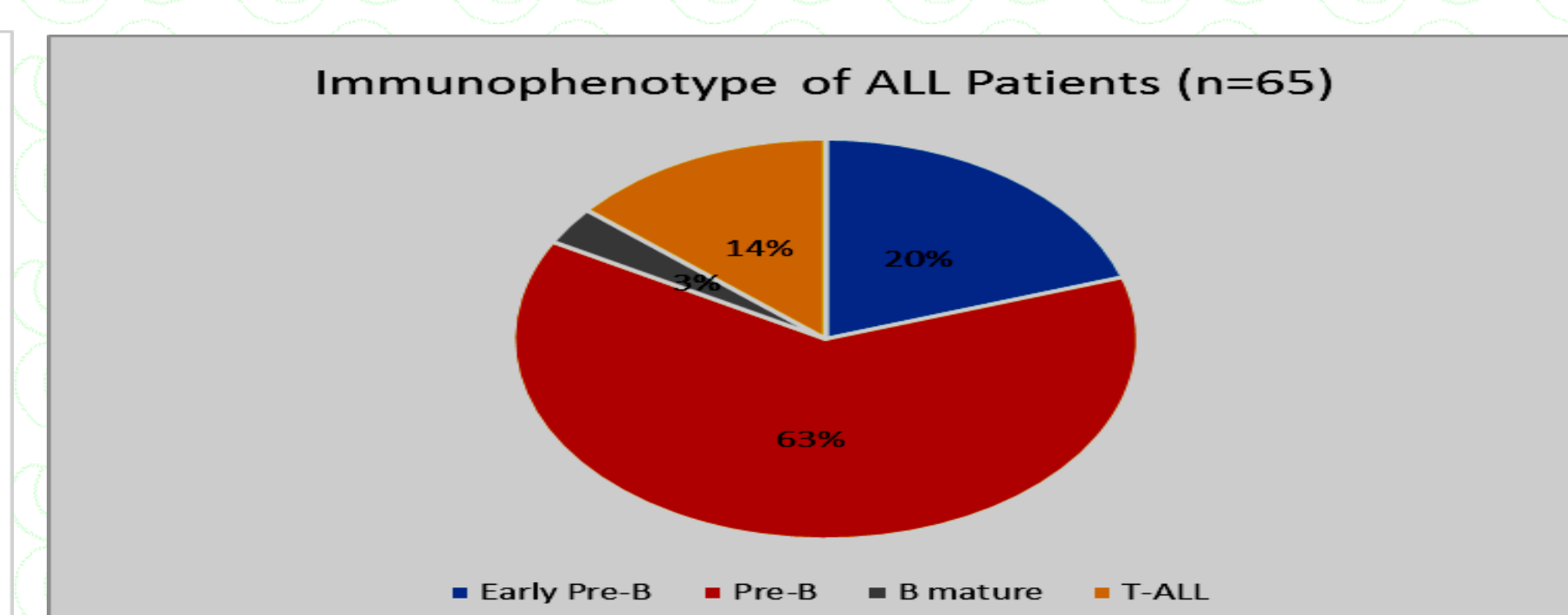


Figure 4: Flow Cytometry in ALL Patients

Treatment	n (142)	%
Chemotherapy	142	100%
BFM-90	89	62.67%
MCP-841	53	37.33%

Table 1: Treatment Protocol in Acute Lymphoblastic Leukemia Patients

SGPT (ALT)	n (142)	%
< 5	0	0%
5-40	79	55.63%
> 40	63	44.37%

Table 2: Baseline SGPT level in Acute Lymphoblastic Leukemia patients

	Early Pre-B (n=13)	Pre-B (n=41)	B mature (n=2)	T-ALL (n=9)
CR	100 %	100 %	50 %	77.78 %
OS	100 %	100 %	100 %	77.78 %
EFS	55.76 %	57.43 %	58.72 %	56.89 %

Table 3: Correlation of Immunophenotype with CR, OS and EFS in Acute Lymphoblastic Leukemia

Platelet (× 10 ³ /cmm)	n (142)	%
0-100	71	50%
100-200	25	17.60%
200-300	28	19.71%
300-400	13	9.15%
> 400	5	3.52%

Table 4: Baseline Platelet Count in Acute Lymphoblastic Leukemia Patients

Follow up (year) at the end	No. of patients alive	% Alive
1 year	88	61.97%
2 year	23	16.19%
3 year	18	12.67%
4 year	7	4.92%
Total	136	95.75%

Table 5: Overall Survival in Acute Lymphoblastic Leukemia patients

Sr. No.	Follow up (year)	n (142)	Event free survival
1	1 year	90	56.25%
2	2 year	27	56%
3	3 year	18	60.29%
4	4 year	07	64.16%
	Mean	142	59.18%

Table 6: Event Free Survival in Acute Lymphoblastic Leukemia Patients

	BFM-90 (n=89)	MCP-841 (n=55)
CR* achieved	96.62%	83.63%
OS [§]	97.75%	92.72%
EFS [#]	62.22%	56.12%
Events		
Abdominal pain	63	39
Joint pain	79	49
Back pain	69	34
Diarrhoea	42	28
Deaths	2	4
Infection	2	3
Seizure	0	1
Rs. Per day	130	80
Duration of therapy (months)	6	12

Table 7: Comparison of BFM-90 and MCP-841 treatment protocol in Acute Lymphoblastic Leukemia patients.

*CR-Complete Remission, [§]OS- Overall Survival, [#]EFS- Event Free Survival

CONCLUSION

Complete remission, overall survival and event free survival rates achieved represent a significant improvement in ALL patients. Age, Hb, WBC and platelet define the risk group suggesting the prognostic features for ALL patients in India. Complete Remission achieved in BFM-90 protocol was high as compared to MCP-841 protocol.