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HCC REPORT 2022



https://www.hemecancer.org/

MESSAGE FROM DIRECTOR

Hematological cancers are one of the most curable cancers if diagnosed early and treated appropriately. The delivery of treatment in our country has several limitations which include but are not limited to resource constraints, lack of expertise and knowledge to deliver therapy. While India has highly skilled professionals in the medical and basic science institutes and numerous institutions that are on par with international peers, these are often limited to major cities and



are inaccessible to the poor. The overall number of trained educated health workers is very low in proportion to the country's population. It is widely recognized that there is significant under diagnosis of hematological cancers in India and of those diagnosed, a substantial proportion of patients do not receive standard of care therapy. Many of the issues have never been systematically evaluated due to the lack of large well-annotated registry data. Also, treatment strategies and algorithms are often based on studies and data generated in high-income countries, usually in the setting of a clinical trial, with a different health care delivery system which may not necessarily be applicable in India.

Hematology Cancer Consortium is a multi-center collaborative academic organization established with the aim to improve knowledge, standardized treatment protocols, and cost-effective approaches to management based on locally generated data.

We began with 12 leading Cancer Centers as our institutional partner and we currently have 17 partners. We have established a collaborative database for acute leukemia's and lymphoma's and have started conducting prospective investigator-initiated studies.

We are grateful to the donors and our institutional partners for their support.

DR. VIKRAM MATHEWS

DIRECTOR,
HEMATOLOGY CANCER CONSORTIUM



WHO ARE WE

Hematology Cancer Consortium (HCC) is a multi center collaborative organisation established to fulfil the long felt need of good quality, cooperative group data in hematological malignancies in India.

Our Goals

- Aggregate clinical data to support care outcomes of hematological malignancies
- Develop evidence based, locally relevant treatment protocols and guidelines
- Run investigator initiated prospective collaborative clinical trials addressing regionally relevant questions and evaluating cost effective treatment strategies
- Continuous education to improve awareness and enhance knowledge of therapeutic options for standardization of care in hematological cancers



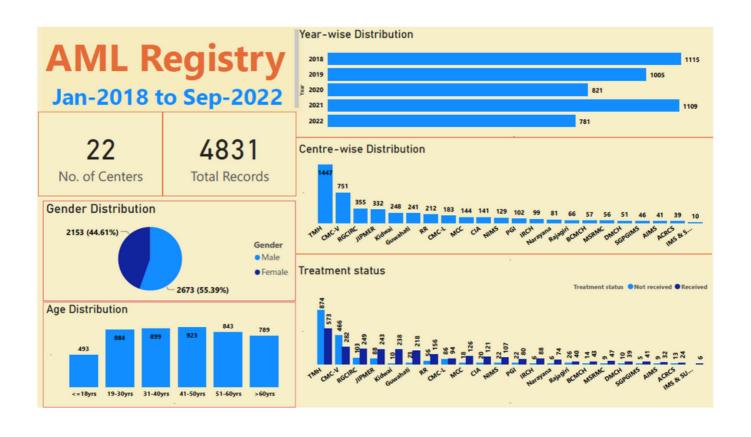


HCC REGISTRY

One of the goals of Hematology Cancer Consortium is to aggregate clinical data to support care outcomes of hematological malignancies.

The below graph summarizes the total data recorded across all the centers till September 2022 with center-wise distribution and yearly progression.

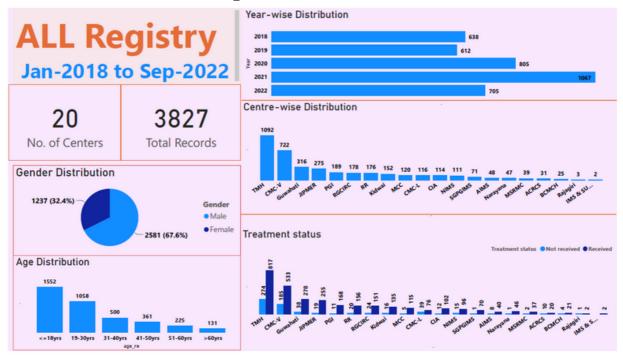
Acute Myeloid Leukemia: 22 centers across the country recorded 4831 patients' information.





HCC REGISTRY

<u>Acute Lymphocytic Leukemia:</u> 20 centers across the country recorded 3827 patients' information.



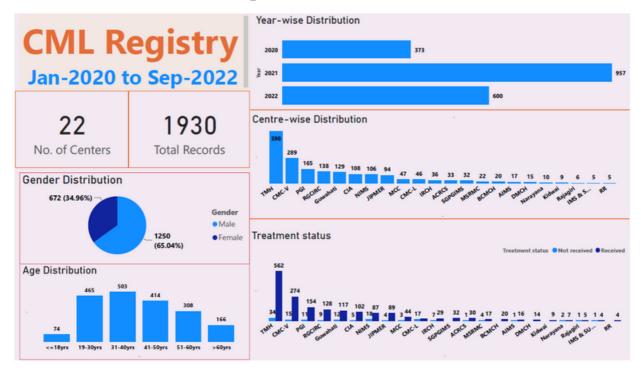
<u>Acute Promyelocytic Leukemia:</u> 22 centers across the country recorded 511 patients' information.



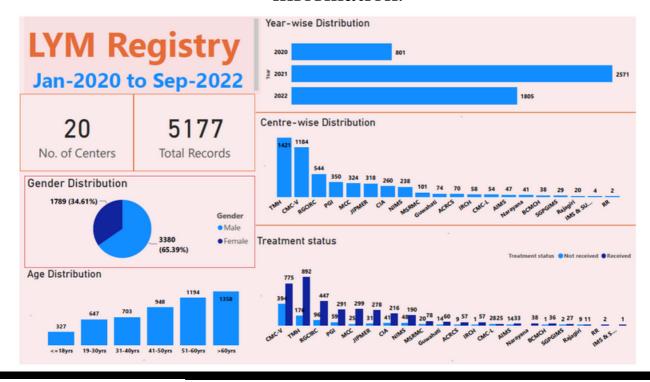


HCC REGISTRY

<u>Chronic Myeloid Leukemia:</u> 22 centers across the country recorded 1930 patients' information.



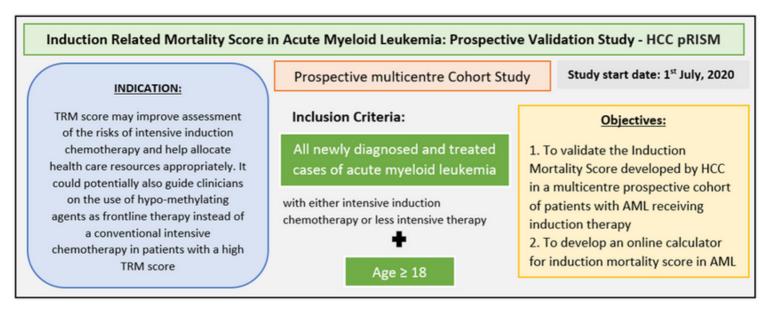
<u>Lymphoma:</u> 20 centers across the country recorded 5177 patients' information.



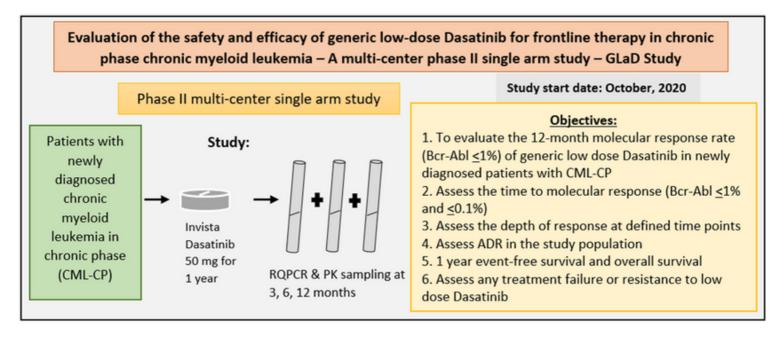


RESEARCH

<u>Title:</u> Induction Related Mortality Score in Acute Myeloid Leukemia: Prospective Validation Study



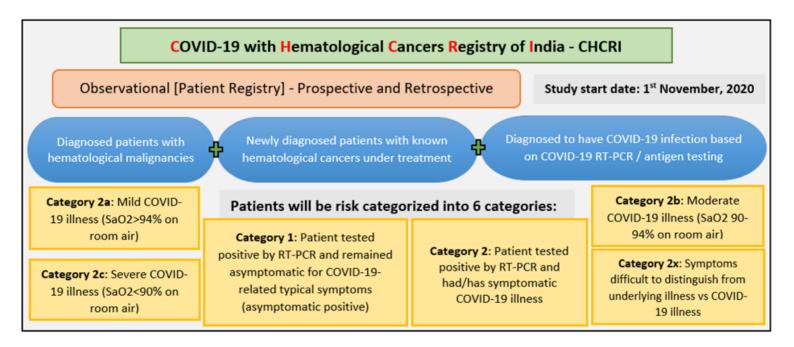
<u>Title:</u> Evaluation of the safety and efficacy of generic low-dose Dasatinib for frontline therapy in chronic phase chronic myeloid leukemia - A multi-center phase II single arm study



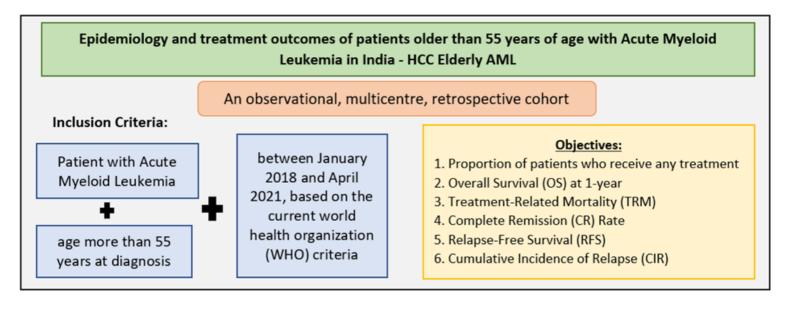


RESEARCH

Title: COVID-19 with Hematological Cancers Registry of India (CHCRI)



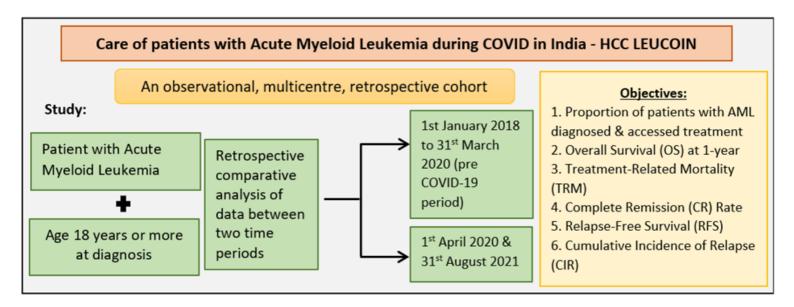
<u>Title:</u> Epidemiology and treatment outcomes of patients older than 55 years of age with Acute Myeloid Leukemia in India



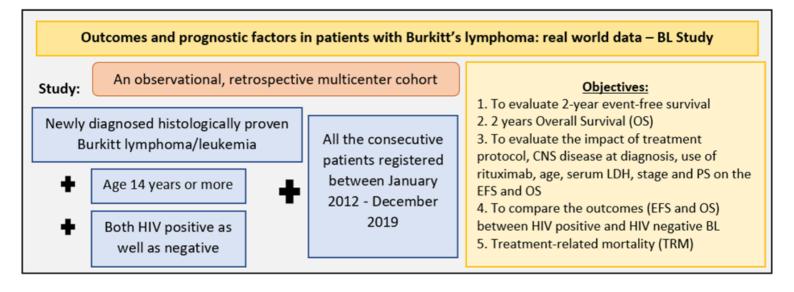


RESEARCH

<u>Title:</u> Care of patients with Acute Myeloid Leukemia during COVID in India



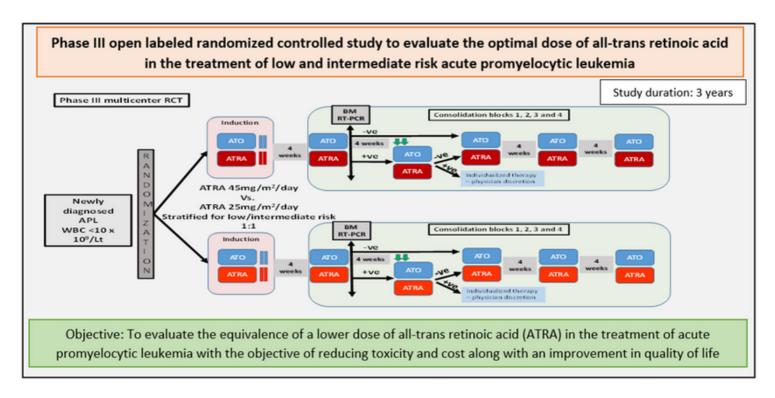
<u>Title:</u> Outcomes and prognostic factors in patients with Burkitt's lymphoma: real world data





UPCOMING RESEARCH

<u>Title:</u> Phase III open labeled randomized controlled study to evaluate the optimal dose of all-trans retinoic acid in the treatment of low and intermediate risk acute promyelocytic leukemia





EDUCATION & TRAINING

WEBINAR SERIES: APRIL - DECEMBER 2022

TOPIC: LEVERAGING T-CELL ENGAGING IMMUNOTHERAPY FOR THE TREATMENT OF ACUTE LYMPHOBLASTIC LEUKEMIA

IN ASSOCIATION WITH
SOCIETY OF HEMATOLOGIC ONCOLOGY (SOHO) AND
PHYSICIANS' EDUCATION RESOURCE® (PER®)

SPEAKERS

Elias Jabbor, MD

MD Anderson Cancer Center, Houston, TX, USA

Nikita Mehra, MD, DM

Cancer Institute (WIA), Adyar, Chennai, India

Hagop M Kantarjian, MD

MD Anderson Cancer Center, Houston, TX, USA

Prasanth Ganesan, MD, DM JIPMER, Puducherry, India

In addition to this HCC has conducted webinars on various topics

Topic	Speaker(s)	
Common challenges in management of hematological malignancies in COVID era	Multiple speakers	
Current Evidence in Management of CLL & Future Direction	Dr. Nitin Jain , MD Associate Professor Department of Leukemia MD Anderson Cancer Center Houston, TX	
What can our chromosomes tell us? Relevance of cytogenetic assessment in hematological malignancies	Dr.Nancy Beryl Janet . A Lecturer, Department of Haematology CMC, Vellore	
A Primer on Molecular Testing in Haematology & MRD in AML	Dr. Madhavi Maddali , MD, DNB, Assistant Professor, Department of Haematology CMC, Vellore	
Overview of Cytomorphology in Hematological Malignancies	Brig Tathagata Chatterjee , COL S Venkatesan	



EDUCATION & TRAINING

Cont..

Topic	Speaker(s)	
Immunophenotyping: Basic Interpretation for a Clinician	Dr. Prashant Tembhare , Hematopathology Laboratory, ACTREC, Tata Memorial Center	
ASH 2020 Update	Multiple Speakers	
How to evaluate flow and interpret flow cytometry based MRD	Dr. Prashant Tembhare , Hematopathology Laboratory, ACTREC, Tata Memorial Center	
What's new in CLL - ASH 2020 Updates	Dr. Nitin Jain , MD Associate Professor Department of Leukemia MD Anderson Cancer Center Houston, TX	
How I Define High- Risk CLL	Prof Ritu Gupta , Professor & Officer-In-Charge, Laboratory Oncology, AIIMS, New Delhi	
How I Treat CLL	Dr. Pankaj Malhotra, PGI, Chandigarh	
COVID Vaccination and Hematological Cancers	Dr. Priya Sampathkumar , MD, Division of Infectious Disease, Mayo Clinic	

SOP'S FOR CONDUCTING MULTICENTER TRIALS

Standard Operating Procedures (SOP) for conducting a multicenter trial have been developed and are available on the HCC website.

- SOP 1 How to screen a study for a multicenter trial
- SOP 2 Screening a site for eligibility
- SOP 3 Site initiation checklist
- SOP 4 Monitoring the trial
- SOP 5 How to respond to the monitoring report from the CRO
- SOP 6 Approach to establish authorship in a multicentric clinical trial



TRAINING PROGRAM FOR DEO

HCC conducted training programs for our Data Entry Operators in collaboration with the BIRAC, CDMC & NCG teams.

BIRAC team conducted 12 training programs on various topics.

ICMR Guidelines	Clinical Trial Monitoring	Source Documents
Essential Documents	ICH GCP guideline E6 R2	Investigator responsibilities
Sponsor Responsibilities	Investigational Product Management	Root Cause Analysis (RCA) and Corrective and Preventive Actions (CAPA)
Safety Reporting in CTs	Audits	Audit and Inspection

DEOs also attended the "Clinical Research Methodology - CRM 2021" workshop organized by Tata Memorial Center in the month of October 2021. Topics were:

Generating a Research Question	PubMed Search	Phases of Clinical Trials	
Randomization	Study Designs	Protocol/Aims/Objectives/ Methods	
Why Statistics, p-value, Errors, Sample size and Standard Error	Which Stats test where?	Measures Of Association - Odds Ratio And Relative Risk	
Diagnostic tests	ICD and IC Process	Survival analysis	
Meta-Analysis	Electronic Data Base and SPSS	Making a CRF	
Referencing styles	Medical Writing- Publication and posters		



TRAINING PROGRAM FOR DEO

A special workshop for DEO's was conducted on 6th & 7th August 2021.

Basics about Hematologic cancers

Dr. Uday Kulkarni

Overview & explanation of terminologies used in software

AML : Dr Smita Kayal

ALL : Dr Prasanth Ganesan
CML : Dr Hasmukh Jain
APML : Dr Uday Kulkarni
Lymphoma : Dr Anu Korula

Introduction to data collection, basic biostatistics and terminologies

Dr Jeyaseelan

Hands on experience on the software

Mr Omprakash

We conducted DEO training program on 27th and 28th May 2022 in collaboration with the CDMC team.

Basics about Hematologic cancers	Dr. Manju Sengar
CDMC: Data collection system & Data quality	Dr. Prasanna Samuel
HCC online platform & Pitfalls in data collections with examples	Mr. Omprakash
Overview & explanation of terminologies	
used in software:	
APML	Dr. Hasmukh Jain
ALL	Dr. Prasanth Ganesan
AML	Dr. Manju Sengar
CML	Dr. Rajan Kapoor
Lymphoma	Dr. Anu Korula

Training program recordings are now available on the HCC website.



NURSING WEBINAR

HCC nurses group had initiated an education program to enhance knowledge. Webinars are held on the last Tuesday of every month.

Topic	Speaker	
CVAD- PICC Insertion care & maintenance	Ms. Sheelpa N Raskar, Sr. Nurse Department of CVAD, Tata Memorial Hospital, Mumbai	
Role of immunotherapy in cancer treatment	Mrs. Abijah Princy B, Nurse Manager, Hemato- Oncology Nursing Department, CMC Vellore	
Transforming nursing practice: Nursing Research	Mrs. Sangeetha Samuel, Deputy Nursing Superintendent / Assistant Professor, Christian Medical College & Hospital, Ludhiana	
Nursing management of side effects of chemotherapy	Mrs. Reena Nair, ANS, Tata Memorial Hospital, Mumbai	
Clinical transfusion practices for nurses	Ms. Manisha U G, Staff Nurse, ACTREC, Tata Memorial Center, Navi Mumbai	
How to write a research proposal	Dr. Venkatraman Radhakrishnan, Professor & In-charge Medical Oncology, Cancer Institute (W.I.A)	
Role of car t - cell therapy in hematological malignancies	Mrs. Abijah Princy B, Nurse Manager, Department of Hematology, CMC Vellore	
Role of nurses in apheresis	Ms. Josephine Suganya AMC, Apheresis Nurse, Hemato- Oncology Nursing Department, CMC Vellore	
Recognition and management of early complication in allogenic HSCT: Nursing Perspective	Ms. Mita Roychowdhury, Clinical Nurse Specialist, Bone Marrow Transplant Unit, TMC, Kolkata	



NURSING WEBINAR

Cont..

Topic	Speaker
Childhood and Young All Sticking to Protocol - A Nursing Perspective	Capt Monika, BSC nursing, Diploma in oncology nursing and Lt Gunjan Rawat, BSC (hons) nursing, Hematology daycare and BMT, Command Hospital, Kolkata
Role of Nurses in Bone Marrow Transplant	Ms. Sindhu S, BMT Incharge, Malabar Cancer Center, Thalassery, Kannur, Kerala
PICC, Insertion, Care and Maintenance	Ms. Jyothi Vidya, Senior Registered Nurse, HCGMSR Cancer Hospital, Bangalore
Common Investigations in Hemato- Oncology (BMT)	Ms. Preethi S, Nursing Officer, JIPMER, Puducherry
Extravasation it's Prevention and Management	Ms. Surya Sukumaran, Senior Nurse Educator, Rajiv Gandhi Cancer Institute and Research Center, Delhi
Palliative Nursing Improving Quality of Life of Oncology Patients	Ms. Rekha Kuchekar, Palliative Care Nurse, TMH, Mumbai

Webinar recordings are available on our website:

http://hemecancer.org/

Register as a member to access recordings:

http://hemecancer.org/webinar-recording.php



PUBLICATIONS

Outcomes in adolescent and young adult acute lymphoblastic leukaemia: a report from the Indian Acute Leukaemia Research Database (INWARD) of the Hematology Cancer Consortium (HCC)

British Journal of Haematology

https://www.hemecancer.org/pdf/bjh.17268.pdf

DOI: 10.1111/bjh.17268

Hematological Cancer Consortium: Multi-Center Acute Myeloid Leukemia Registry Data from India

Blood 2018; 132 (Supplement 1): 4006.

https://doi.org/10.1182/blood-2018-99-116853

Outcomes of patients with hematologic malignancies and COVID-19 from the Hematologic Cancer Registry of India

Blood Cancer Journal https://doi.org/10.1038/s41408-021-00599-w



ABSTRACTS SELECTED BY ASH FOR POSTER PRESENTATION

Abstract ID#: 169777

Low Dose Dasatinib Is Not As Active in a CML CP Cohort Enriched with Intermediate/High-Risk CML Chronic Phase: A Phase IIb Multi-Center Trial

Aby Abraham, MD, DM, Hasmukh Jain, MD, DM, Jina Bhattacharyya, MD, DM, Dubashi Biswajit, MD, DNB, DM, Jayachandran PK, MD, MRCP, DM, Dinesh Bhurani, MD, DM, FRCPA, Stalin Chowdary Bala, MBBS, MD, DM, DNB, Suman Pramanik, MD, Santhosh Devadas, Uday Prakash Kulkarni, MD, DM, Manju Sengar, MD, DM, RayazAhmed, MD, DM, Thenmozhi Mani, PhD, Damodar Das, MD, Parathan Karunakaran, MD, DM, Sadashivudu Gundeti, MD DM, Rasmi Pallasseri, Nikhil Patkar, MD, Manjunath Nookala, MD and Poonkuzhali Balasubramanian, MSc, PhD

Department of Haematology, Christian Medical College, Vellore, India; Adult Hematolymphoid Disease Management Group, Department of Medical Oncology, Tata Memorial Centre, Mumbai, India;

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Department of Medical Oncology, Jawaharlal Institute of Postgraduate Medical Education & Research (JIPMER), Puducherry, India;

Department of MedicalOncology, Cancer Institute (WIA), Chennai, India; Department of Hemato-Oncology & BMT, Rajiv Gandhi Cancer Institute and Research Centre, NewDelhi, Madhya Pradesh, India;

Department of Medical Oncology, Nizam's Institute of Medical Sciences, Hyderabad, India;

Army Hospital (Research& Referral), New Delhi, India;

Department of Medical Oncology, MSRamaiah Memorial Hospital, Bengaluru, IND;

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Department of Hemato-Oncology & BMT, Rajiv Gandhi Cancer Instituteand Research Centre, New Delhi, India;

Department of Biostatistics,



ABSTRACT ID#: 169777

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Department of Haematology, Guwahati Medical College, Guwahati, India;

Nizam's Institute of Medical Sciences, Hyderabad, India;

Department of Oncology, MS RamaiahMedical College, Bengaluru, India;

Hematopathology Laboratory, TataMemorial Centre, Mumbai, India;

Haematopathology Laboratory, TataMemorial Hospital, Tata Memorial Centre,

Affi liated to Homi BhabhaNational Institute, Navi Mumbai, India;

Hematopathology Laboratory, ACTREC, Tata Memorial Centre, Navi Mumbai, India;

ClinicalPharmacology, Advanced Centre for treatment research and education incancer, Panvel, India;

Christian Medical College, Vellore, IND

<u>Background-</u> A lower dose of Dasatinib has been shown to have excellent results in CML in CP, even better than standard doses in a single-center study using the innovator drug (Naqvi et al, Cancer, January 2020). We conducted a multicenter trial using a lower dose of generic Dasatinib (Invista, Dr. Reddy's, Hyderabad, India) to see the outcomes.

Methods- This is a phase II multi-center investigator initiated study conducted between October 2020 till September 2021. Patients were enrolled from 9 centers across India. The inclusion criteria were CML in CP, aged 18-60 years without any co-morbidities and another cancer. They were enrolled in the trial after a written informed consent. Initial assessment included complete blood counts, bone marrow examination including karyotype, FISH for t (9;22) and serum chemistries. They were given 50 mg daily of generic Dasatinib. Blood counts were monitored once in 1-2 weeks for the fi rst 2 months and monthly thereafter. Dasatinib drug levels and RQPCR was monitored at 3-, 6- and 12-month intervals. The response was defined as per ELN 2020 criteria. The main outcome measure was CCyR (or equivalent molecular response </=1%) at 12months, the secondary outcome measures included MMR and EMR. Patients who did not tolerate or progressed while on Dasatinib were switched to Imatinib or one of the other TKIs while those who failed at 6months were switched to standard dose Dasatinib.

Results- Out of the 207 patients who were screened, 90 patients were enrolled into the trial of which 70 (77.8%) were men. The median age was 36.5 years (29-50). The distribution of patients as per Sokal score and ELTS were 35 (39.3%) for high, 44(49.4%)/37(41.6%) for intermediate and 10(11.2%)/17(19.1%) for low risk respectively

With a median follow-up of 11(6,12) months, 80 (88.8%), 71 (78.8%) and 39(43.3%) patients completed 3,6 and 12 months of therapy and the results are available currently. Optimal response at 3, 6 and 12 months as per ELN 2020 criteria was achieved by 44/80 (55%), 42/71 (59.1%) and 19/39(48.7%) patients.



ABSTRACT ID#: 169777

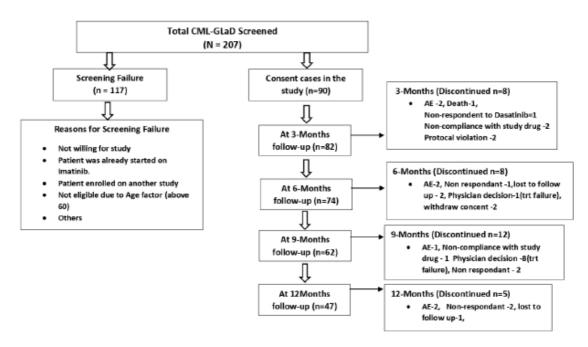
EMR at 3 months was achieved by 44/80 (55 %) patients. CCyR was achieved by 42/71 (59.1%) at 6 months and 35/39 (89.7%) at 12 months. MMR was achieved by 17/71 (23.9%) and 19/39 (48.7%) patients respectively.

A total of 53 patients developed at least one adverse event. A total of 199adverse events were recorded, out of which only 13 (6.5%) were of grade¾. The most common toxicity events were hematological (14), gastrointestinal (55), headache (17) and cough (11). The most common grade ¾ toxicities were hematological (8 events). There were 4 serious AEs during the trial-hematological (2), Ileus (1) and disseminated varicella (1). Toxicities led to a dose reduction in 2 patients and interruption in 18 patients.

<u>Discussion-</u> This is the fist multicenter investigator initiated clinical trial involving nine centers from India on Chronic myeloid Leukemia. This reflects the challenges involved in conducting multicenter study like recruitment, patient compliance and default. The CCyR of 89.7% inpatients who have completed 12 months of therapy appears promising. The toxicity is comparable to previous studies. The higher proportion of high and intermediate risk patients in this cohort could probably account for the less than expected results compared to previously published data with low dose Dasatinib.

<u>Conclusion-</u> At this interim analysis Dasatinib 50 mg appears to be promising with respect to responses but with a caution considering the fact that the majority of patients had a higher disease load. We need to wait for the fi nal results before Dasatinib 50 mg can be considered as standard of care.

Flow Chart of recruitment





Abstract ID#: 165840

Prognostic Factors and Outcomes of Adolescent and Adult Burkitt Lymphoma and Leukemia from a Low-Middle Income Country: An Experience from Hematology Cancer Consortium

Manju Sengar, MD, DM, Anu Korula, MD, DM, Prasanth Ganesan, MD, DM, Akhil Rajendra, MD, Hasmukh Jain, MD, DM, Prasanna Samuel, MSc, PhD, Jayachandran P K, MD, DM, Gaurav Prakash, MD, DM, M. Joseph John, MD, DM, Rasmi Palassery, MD, Chandran K. Nair, MD, DNB, DM, Tanuja Shet, Sushil Selvarajan, MD, DM, Lingaraj Nayak, MD, DM, Parathan Karunakaran, MD, DM, Fouzia NA, DNB, DM, Om Prakash, MSc, Bhausaheb Bagal, MD, DM, Nikita Mehra, MD, DM, Saranya Kumaran, Sridhar Epari, Jayshree Thorat, MD, Venkatraman Radhakrishnan and Aby Abraham, MD, DM

Homibhaba National Institute, Mumbai, India, MUMBAI, India; Department of Haematology, Christian Medical College, Vellore, India; Department of Medical Oncology, Jawaharlal Institute of Postgraduate Medical Education & Research (JIPMER), Puducherry, India; Department of Medical Oncology, Tata Memorial Centre, Mumbai, Alabama, India; Department of Medical Oncology, Tata Memorial Centre, Mumbai, India; Department of Biostatistics, Christian Medical College, Vellore, Vellore, India; Cancer Institute(WIA), Adyar, Chennai, India; Department of Clinical Hematology and Medical Oncology, Postgraduate Institute of Medical Education and Research, Chandigarh, India; Department of Clinical Haematology and BMT, Christian Medical College & Hospital, Ludhiana, India; Ramaiah Medical College and Hospital, Ramaiah Medical College and Hospital, Bengaluru, OH, India; Department of Clinical Hematology and Medical Oncology, Malabar Cancer Centre, Thalassery, IND; Department of Pathology, Tata Memorial Centre, Aaliated to Homi Bhabha National Institute, Mumbai, India; Department of Haematology, Christian Medical College, Vellore, Tamil Nadu, India; Department of Medical Oncology, Cancer Institute (WIA), Chennai, India; Department of Biostatistics, Christian Medical College, Vellore, India; Department of Medical Oncology, Tata Memorial Centre, Mumbai, Maharashtra, India: CDMC, Christian Medical College, Vellore, Vellore, India; Tata Memorial Hospital, Mumbai, India; Adult Hematolymphoid Management Group, Tata Memorial Hospital, Mumbai, Mumbai, Maharashtra, India; Department of Haematology, Christian Medical College, Vellore, Vellore, Tamil Nadu, India



ABSTRACT ID#: 165840

The treatment of BL/L has evolved on the principles of short-course, intensive, non-cross resistant, alternating chemotherapy. These intensive high-dose methotrexate-based treatment regimens (CODOXM/IVAC, Hyper-CVAD, BFM, LMB) have led to high response rates and cures in a significant proportion of children and young adults. The addition of rituximab has led to overall survival benefit. There is limited data that dose adjusted EPOCH-R provides a low intensity treatment option for patients who may not be able to tolerate high-dose methotrexate-based regimens. Efficacy of these regimens in real-world, more so in an LMIC setting need to be evaluated given the delays in seeking care, higher risk of treatment-related complications including infections and antecedent treatment interruptions.

This retrospective multicentric study collected the data from eight member centers of Hematology Cancer Consortium (www.hemecancer.org) using an electronic database, to analyze the clinical characteristics, treatment patterns, outcomes and prognostic factors in adolescent and adult newly diagnosed Burkitt lymphoma and leukemia diagnosed between 2012-2019 (including HIV positive). Patients who had received more than 2 weeks of chemotherapy or steroids prior to presentation were excluded. The data included demographic details, performance status (ECOG), HIV serology, bone marrow and CNS involvement, stage, treatment type, use of rituximab, response to treatment, and treatment-related mortality as assessed by the investigator of the respective centre. The primary objective was to evaluate event-free survival at 2 years. Secondary objectives were to evaluate the overall survival, impact of the treatment protocol, use of rituximab, stage, age, performance status, CNS involvement, and HIV positive status on the overall and event-free survival.

A total of 312 patients were included in this study. Out of these 257 patients received treatment and were analyzed for the outcome and prognostic factors. The treated and untreated cohorts differed in age [median age 37 years (range-25-49 years) versus 42 years (range-32-51 years); with the untreated cohort being older. Table 1 provides the baseline characteristics of the patients who received treatment. The HIV positive patients (in treated cohort) had higher LDH [median - 967.5 (range, 509- 2355) vs 589 (311-1141),

p=0.003). A total of 100 (42%) patients received intensive and high-dose methotrexate-based chemotherapy, 81 (34%) patients received dose-adjusted EPOCH-based treatment whereas 56 (24%) received other low-intensity or palliative chemotherapy. Patients with HIV were largely treated with a dose adjusted EPOCH-based regimen (25/32 patients). Patients who received a high-dose methotrexate-based regimen were younger than those who received dose-adjusted EPOCH and other lower intensity regimens (Mean age 29 years versus 42.4 and 43.9 years)

At the median follow-up of 36.5 months, the 2-year EFS was 61% and 2- year OS was 73%. There was no significant difference in outcomes in HIV-positive and negative patients. On univariate analysis lack of use of rituximab and use of protocols other than high-dose methotrexate and dose-adjusted EPOCH negatively



ABSTRACT ID#: 165840

affected EFS and OS. Age had an adverse impact on the OS but not EFS whereas stage 2 or above had a negative impact on EFS. On multivariate analysis use of regimens other than high-dose methotrexate-based and dose-adjusted EPOCH was a negative prognostic factor for both EFS and OS. The HR favored high dose methotrexate and dose-adjusted EPOCH-based regimen for both EFS and OS; HR- 0.42 (95% CI,0.22,0.77) and 0.27(95% CI,0.13-0.59), respectively. Use of rituximab was associated with better OS HR- 0.44(95% CI,0.21-0.93) and a trend toward better EFS – HR-0.58 (95%CI, 0.31-1.07). The treatment-related mortality was 11.2% (29/257) and high serum LDH was associated with higher mortality (p=0.003).

Treatment of adolescent and adult Burkitt lymphoma and leukemia with intensive regimens (high-dose methotrexate-based) and dose adjusted EPOCH regimen resulted in similar survival. Dose-adjusted EPOCH-based regimen was preferred in older patients. The use of rituximab in these patients adds to the overall survival benefit.

Table 1: Characteristics of treated and untreated participants

Variables	Treated (n=257)	Not treated (n=55)	P Value	
Age (yrs)	Median -37 (IQR-25,49)	Median 42 (IQR-32-51)	0.037	
Gender				
Male	193 (75.1%)	42(76.4%)		
Female	64 (24.9%)	13(23.6%)	0.843	
	Median -9000 (IQR -			
WBC (per cumm)	7000,11140)	Median-8550 (IQR 6750,11350)	0.726	
Albumin (g/dL)	Median-3.74 (IQR 3.2-4.2)	Median-3.8 (IQR 3.4 -4.2)	0.096	
LDH (IU/L)			0.204	
HIV	,			
+ve	37(14.4%)	11(20.8%)		
-ve	212(82.5%)	38(71.7%)		
Not done 8 (3.1%)		4(7.5%)		
Stage				
1	25 (9.7%)	4(7.4%)		
2	47(18.3%)	2(3.7%)		
3	32(12.5%)	5(9.3%)		
4	140(54.5%)	19(35.2%)		
Not available	ot available 13(5.1%) 24(44.4%)		0.001	
CNS				
Yes	25(9.7%)	4(7.3%)		
No	177(68.9%)	17(30.9%)		
Not done	55(21.4%)	34(61.8%)	0.001	
Type				
BL	237 (92.2%)	53(96.4%)		
Burkitt leukemia	20(7.8%)	2 (3.6%)		

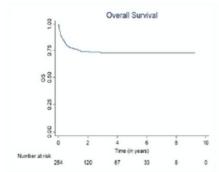


Figure 1: Overall survival for the entire treated cohort of Burkitt lymphoma and leukemia



Abstract ID#: 165770 Acute Myeloid Leukemia during the COVID Pandemic: Impact and the Indian Experience

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ABSTRACT ID#: 165570

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The coronavirus (COVID -19) pandemic posed critical challenges for public health, research, diagnosis, and treatment globally. Beyond the existing challenges in the management of Acute Myeloid Leukemia (AML) in India; we hypothesized that the COVID pandemic would lead to a collateral impact on the management of AML in our setting. Identifying with this goal; we analyzed data utilizing the Indian Acute Leukemia research database [INWARD] established in 2018 by the Hematology Cancer Consortium (HCC).

Retrospective analysis of data for adult AML collected from 17 member institutions through a central online data management system was compared through two time periods: the pre-COVID period (1st January2018 through 31st March 2020) and the COVID pandemic period (1st April2020 through 31st August 2021). Survival and follow-up data were analyzed as on 31st May 2022.

A total of 2998 patients, were registered (2003 in the pre-COVID period and 995 during the COVID pandemic), Fig 1. The average patient registrations per month were 74 ± 11 and 59 ± 19 , P < 0.05 respectively. In comparison, 978(28.7%) patients in the pre-COVID period and 612 (61.5%) patients during the COVID pandemic received treatment. In those who underwent treatment during the pandemic; 357(58.5%) received intensive (7+3 based) induction and 210 (34.4%) received hypomethylating agent-based therapy. They included 165 (26.6%) patients who had concurrent infections needing antibiotics at presentation. 336(54.9%) patients developed febrile neutropenia, with an organism isolated in the blood in 110 (32.7%) patients. Fungal infection was noted in 126 (20.5%) patients; proven in 8(6.3%). There were 87 (14.4%) patients needing admission to an intensive care unit. Inotrope was needed in 57 (9.3%) patients and mechanical ventilation for 38(6.2%) patients. 172 (28.1%) patients received further consolidation; with high (3g/m2) dose cytarabine in 127 (73.8%) of them. Additionally, 52 (8.5%) patients underwent a stem cell transplant.

In comparison to patients receiving treatment in the pre-COVID period; the demographic features, rates of documented bloodstream infection, ICU stay, requirements for mechanical ventilation, and use of inotropes were comparable to patients during the pandemic. However, we noted that the differences [pre-COVID vs during the pandemic] in the use of hypomethylating agents [298 (30.4%) vs 210 (34.3%)], targeted drugs [27(2.7%) vs 43 (7.0%)] febrile neutropenia [621 (63.5%) vs 336 (54.9%)], fungal infections [297 (30.3%) vs 126 (20.5%)], concurrent infection [325 (33.2%) vs165 (26.6%)] and use of central venous access [598 (61.1%) vs



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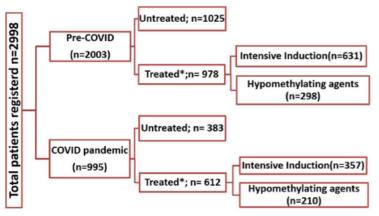
310 (50.6%)]were statistically significant. Among patients who underwent transplants; the intensity of conditioning, remission status, and GvHD were comparable.

The median overall survival (OS) following diagnosis was 549 days and the median event-free survival (EFS) was 363 days for the entire cohort. The median overall survival (OS) during the pre-COVID period was 552 days and 529 days during the pandemic (p = 0.952), Fig 2. The corresponding median EFS was 363 days and 364 days respectively (p = 0.679).

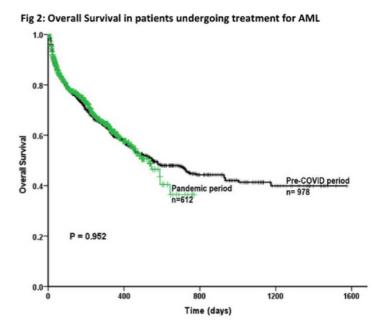
In our experience, although delivering care was challenging; the outcomes for patients who received treatment for AML during the COVID pandemic was comparable with the pre-COVID period. Travel disruption or patient reluctance to visit a hospital during the pandemic might have led to the reduction in patient registrations, though a higher proportion of them received treatment. We hypothesize that the universal embracing of general infection control policies targeting COVID-19 might have driven the observed reduction of fungal and concurrent infection.

Our data suggest that continuing standard of care in treatment-emergent AML even during the pandemic is feasible and intensive induction chemotherapy and transplant should still be offered for eligible patients.

Fig 1: Patient distribution



*Treatments also include non-intensive low dose cytosine





Abstract ID#: 169001

Induction Related Mortality Score in Acute Myeloid Leukemia: Prospective Validation Study (pRISM) of the Hematology Cancer Consortium (HCC)

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Treatment of Acute Myeloid Leukemia (AML) should be initiated at the earliest to improve outcomes. The standard induction regimen (3+7) is associated with significant risk of induction mortality, especially in resource limited settings. Hence there is a need to develop risk prediction model for our patient cohorts. Treatment related mortality (TRM) scoring systems developed and used in developed country, mostly for the elderly, may not be directly applicable to population of young adults in developing countries, many of whom have poor general condition and infections at baseline. We developed a multivariate model of induction mortality score in 2019, from a retrospective AML cohort of the Indian acute leukemia research database [INwARD] established by the Hematology Cancer Consortium (HCC). In the present study we have validated the approach and recalibrated the induction mortality score on a multicenter prospective cohort.

Prospective data for adult AML, for a period of 20 months, starting July2020 to February 2022, was received from 17 member institutions in a central online data management system. Potential variables that would predict mortality were selected based on clinical and statistical significance. Eleven variables relating to baseline patient and disease characteristics (age, ECOG performance status, duration of symptoms in days, albumin, creatinine, bilirubin, white cell count, platelet, hemoglobin, peripheral blood blast percentage, and presence of infection requiring intravenous antibiotic within one week prior of starting induction), were considered for the predictive model using machine learning (ML)algorithms: Logistic regression (LR), Support Vector Machine (SVM) and extreme Gradient Boosting (XGB). Of the various ML algorithms, the best model was chosen based on area under curve (AUC) from the training dataset and validity statistics from the test dataset. We also used the same approach to predict intensive care unit (ICU) admission. R software was used to analyze the data.

Of the 779 treated cases during the study period, 438 received intensive induction, '3+7' being the most common regimen in 80%. The median age of this cohort was 37 years (IQR 28, 46), male to female ratio 1.2.



ABSTRACT ID#: 169001

European Leukemia Net (ELN) risk group was good in 31.3 % (n=137),intermediate in 44% (n=192), high in 13.7% (n=60), and unknown in 11%(n=48). Complete remission was attained in 56.3%. Overall induction mortality was 13.0%, ranging from 7.1% to 40% across different centers. Infection was the most common cause of death in 52%. For predicting induction mortality using 11 covariates, SVM provided the best threshold as 0.126, with an AUC of 94.71%, sensitivity (92.50%), and specificity(96.11%). A comparison of the ML algorithms is shown in Fig 1 and statistics for the SVM model in Table 1. ICU admission was observed in 22.8%; a cut-off threshold of 0.231, with an AUC of 93.3% in the SVM model predicted ICU admission with sensitivity of 93.15% and specificity of 89.7%.

Induction mortality prediction score developed in a retrospective cohort was effectively applied to contemporary prospective data from major centers across the country, with diverse resources and patient profiles. Thus, we have validated the machine learning approach of predicting induction mortality with variables relevant to regional clinical settings including baseline infection. The SVM model predicted the risk of both induction mortality as well as morbidity with high accuracy. An online calculator is being developed to help clinicians use this score in regular practice for guiding treatment intensity as per an individual patient's risk and in directing appropriate resource utilization. Further, the approach of risk-adapted induction intensity, especially for young adult AML, based on the score adjusted to center-specific prevalence of mortality rates, is under consideration for a prospective clinical trial.

Figure 1 ROC (Receiver Operating Characteristic) Curve: Comparison of ML algorithms by AUC (Area under Curve) percentage

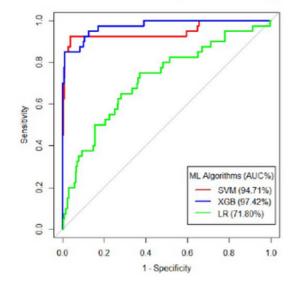


Table 1: Statistics for the SVM Model				
	Train		Test	
	1	Truth	Truth	
Prediction	Dead	Alive	Dead	Alive
Dead	37	10	11	41
Alive	3	247	6	68
AUC	0.95		-	
Threshold	0.126		-	
Sensitivity	92.50		64.71	
Specificity	96.11		62.39	
Accuracy	95.62		62.70	
PPV	78.72		21.15	
NPV	9	98.80	91.89	



Real world data on unique challenges and outcomes of older patients with AML from resource limited settings: Hematology Cancer Consortium INwARD registry

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Despite significant advances in the treatment of acute myeloid leukemia (AML), outcomes in older patients continue to be suboptimal, due to adverse disease characteristics and increasing prevalence of comorbidities. This challenge is further magnified in resource-limited settings where logistical and financial barriers often preclude effective therapy. In addition, a significant number of patients do not undergo any evaluation after diagnosis, resulting in very little real-world data on treatment outcomes in this cohort. We present data on epidemiology and treatment patterns in older patients with AML from the Indian Acute Leukemia Research Database [INwARD] established by Hematology Cancer Consortium (HCC).



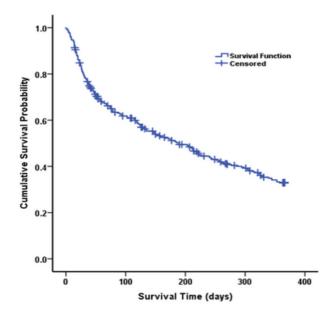
Retrospective data from 17 centres was collected to include patients older than 55 years diagnosed between January 2018 and April 2021.. A lower age cut off of 55 years was used based on previous data indicating physiologic characteristics comparable to a 65 year old individual in the West. No exclusion criteria were specified. The primary objectives were to ascertain the proportion of patients receiving therapy and one-year overall survival among treated patients. Patient status was assessed as on March 31, 2022.

A total of 733 patients (M:F=1.48) were included in this study, of which only 339(46%) patients underwent further evaluation and treatment. The most common reasons for not initiating treatment were to begin evaluation at another centre (37%) and financial constraints(13%). Among treated patients, the median age at diagnosis was 63 years (IQR, 59-69), with 130(40.2%) having an ECOG performance score≥2 and 203(60.4%) having at least one comorbidity. No differences in baseline attributes were noted among treated or untreated patients.(Table 1)Of the 339 patients who received treatment, initial therapy comprised hypomethylating agents (HMA) in 247 (72.8%) patients, standard or modified 7+3 regimen in 64 (18.8%) and other intensive regimens in 2 (0.59%) patients. Infections requiring treatment were diagnosed in 117 (40.3%) patients, with 36 (13.79%) requiring intensive care. A second induction was required in 26 patients, of which 5(19%) received intensive chemotherapy and 8 (30%) received HMA. Early mortality (within 60 days of diagnosis) was noted in 58(20.1%) out of 288 evaluable patients at this time point. Poor performance status at baseline was significantly associated with early mortality (p=0.015) with no effect of age or associated co-morbidities. Among patients who died within 60 days, a significantly higher white cell count was observed at baseline (median, 20310 vs 7200/mm3,p=0.005). Complete remission (CR) was achieved in 24(36%) patients after intensive chemotherapy. Among 146(59%) evaluable patients receiving HMA, 62(42%) achieved CR at any time point after therapy. The probability of achieving CR significantly decreased with increasing age (p=0.037). Allogeneic stem cell transplant was utilized for only 11 (3.2%) patients in the treated cohort.

After a median follow up of 5 months (IQR 1.4 to 14.6 months), 102 (32.2%) patients were lost to follow up and only 72 (26%) had completed treatment. For survival analysis, patients lost to follow up were considered dead at the date of last follow up. At the end of one year, probability of survival was 32.9%, (Figure 1) with the median overall survival being 190 days (95% CI, 143 to 236) in the treated cohort. Among 145 patients with available data, the most common cause of death was progressive disease (52%), followed by infectious complications (29%).

Our data highlights dual challenges of low rates of treatment initiation and significant treatment discontinuation within one year in patients older than 55 years of age with AML in India. Poor disease biology is also highlighted by low rates of CR irrespective of initial therapy and low probability of survival at one year. Financial challenges emerge as major modifiable factors leading to incomplete treatment. This large registry dataset indicates the need for more effective, affordable and safer treatment options for this group of patients.





 $\label{thm:curve} Figure \ 1: Kaplan\ Meier\ curve\ showing\ one\ year\ overall\ survival\ among\ patients\ who\ initiated\ treatment.$

Variable	Group A	Group B
Age in Years (Median, IQR)	63 (59, 69)	63 (59, 69)
Hb, g/dl (Median, IQR)	7.80 (6.60, 9.10)	8 (6.70, 9.30)
TLC at diagnosis in/mm3 (WBC)	8430 (2910, 33700)	11700 (347, 49750)
(Median, IQR)		
Gender	N(%)	N(%)
Male	202 (59.59)	236 (59.90)
Female	137 (40.41)	158 (40.10)
ECOG Performance status	'	
Fully active	39 (12.07)	16 (4.78)
Restricted in physically strenuous	154 (47.68)	179 (53.43)
activity		
Ambulatory and capable of all self	77 (23.84)	66 (19.70)
care	40.440.01	F7 (47 04)
Capable of only limited self care	42 (13.0)	57 (17.01)
Completely disabled	11 (3.41)	17 (5.07)
ELN Risk Group		
Low	51 (16.50)	21 (7.72)
Intermediate	164 (53.07)	61 (22.43)
High	56 (18.12)	32 (11.76)
Unknown	38 (12.30)	158 (58.09)
Infection at Diagnosis (Fungal/Docum	nented)	•
No	64 (71.91)	5 (83.33)
Yes	25 (28.09)	1 (16.67)

Table 1: Baseline characteristics among patients who received treatment (Group A) and patients who did not (Group B)



Abstract ID#: 167202 Real-World Outcomes for Acute Promyelocytic Leukemia: Need to Address Induction Mortality

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Treatment outcomes of acute promyelocytic leukemia (APL) show variation between clinical trials and real-world setting largely due to exclusion of patients who present with major bleeding, severe infections and those who die within the first week. Use of differentiation agent-based therapy for low/intermediate risk group (ATRA and ATO) and limiting anthracycline use to high-risk subgroup has reduced the treatment-related mortality beyond first week. However, use of steroids for treatment of differentiation syndrome and chemotherapy can still increase the risk of infections which can compromise the outcomes, particularly in a setting with high incidence of multi-drug resistant organism and invasive fungal infections. There is a need to identify the predictors of this mortality and ways to reduce it to improve the outcomes.



ABSTRACT ID#: 167202

We analyzed the data for patients with newly diagnosed APL from two large tertiary care centers in India, registered between 2013-2018 to evaluate the outcomes in all risk groups (as per Sanz score), mortality within first 30-days and prognostic factors. Patients with low/intermediate risk were treated with ATRA and ATO based therapy whereas the high-risk group received chemotherapy in addition to ATRA/ATO. We recorded demographic variables, white blood cell count and platelet count at diagnosis, Sanz score, serum albumin, serum creatinine, treatment administered, achievement of morphological complete remission post induction and complete molecular remission post consolidation, relapse and death. The primary outcome was event free survival (EFS) which counted lack of complete remission post induction, lack of complete molecular remission post consolidation, relapse and death as event. The secondary outcomes were relapse-free survival (RFS), overall survival (OS) and induction mortality (death within first 30 days) and assessment of impact of baseline disease and host factors on the EFS, RFS, OS and induction mortality.

A total of 238 patients were included in this analysis. The median age was 34 years (range 2-72 years) with male: female ratio of 1.5:1. At presentation the median WBC count was 6790 per cumm (range 300- 237,000 per cumm) and median platelet counts were 21000 per cumm (3000-266,000 per cumm). As per Sanz score – 12% were low-risk, 48% were intermediate risk and 40% were high-risk. Median fibrinogen levels were 239 (range 36-883). A total of 231 patients received therapy. A total of 204 patients were assessed for response at the end of induction and all but one patient achieved complete response (87.8% as per intention to treat). The rest were not assessable due to death during induction (19) and loss to follow up (15). The induction mortality was 8.2% (infections-6, coagulopathy-9, differentiation syndrome-2 and others-2).170/185(92%) patients achieved post consolidation complete molecular remission. A total of 19 patients relapsed during the follow up (bone marrow-14, CNS alone-2 and combined -3). The median time to relapse was 23.9 months (IQR 13.6-42.9 months).

At a median follow up of 51.2 months,3-year EFS, RFS and OS were 79%,92% and 88%.

There was no statistically significant difference between low, intermediate and high-risk group for any of the survival outcomes. Similarly, age, gender, fibrinogen and albumin at diagnosis did not have any adverse impact. Baseline WBC of >40000/cumm and serum creatinine of >2 mg/dL at diagnosis adversely affected the overall survival with HR of 3.22 (95% CI 1.42-7.29, p-0.005) and 11.9 (95% CI - 2.78-50.82) respectively. However, the number of patients with raised creatinine were very small (n=4). These two factors had adverse impact on induction mortality too (WBC>40,000 per cumm – HR -3.32, 95% CI- 1.31-8.42, p-0.012 serum creatinine >2 mg/dL- HR 14.69, 95% CI-3.36- 64.18, p<0.0001). The survival probabilities at 3, 4 and 5 years using 30-day landmark analysis were 96%, indicating that there are very few deaths after the first 30 days of induction. Fig 1 depicts the overall survival.



ABSTRACT ID#: 167202

This retrospective analysis highlights that ATO+ATRA and minimal anthracycline based therapy has led to similar outcomes in all risk groups and the present need to address induction mortality. High induction mortality in patients with WBC >40,000/cum indicates the potential contribution of infections due to use of steroids to treat differentiation and underlying coagulopathy or a different biology.

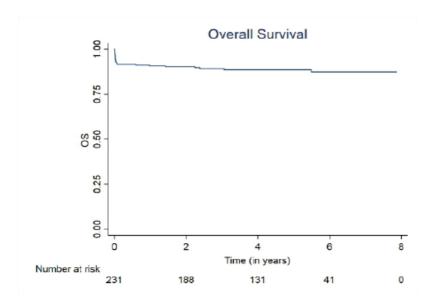


Figure 1: Overall survival for the treated patients



ABSTRACTS SELECTED BY ASH FOR POSTER PRESENTATION 2018

Abstract ID#: 1374

Hematological Cancer Consortium: Multi-Center Acute Lymphoblastic Leukemia Registry Data from India

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ABSTRACT ID#: 1374

Significant strides have been made in the management of ALL and clinical outcomes have steadily improved over the last few decades. Many of these advances involve intensification of therapy, allogeneic SCT, improved molecular risk stratification and measurable residual disease (MRD) directed therapy. However in the developing world and low middle income countries (LMIC) there are significant challenges in implementing or access to such advances. Additionally, in the absence of large collaborative research groups in LMIC, as has been developed in most developed economies, it is difficult to get a handle of the magnitude of the problem and develop strategies to overcome them. The 'Hematological Cancer Consortium' is a collaborative group from India currently comprising of twelve institutions spread across the country that have come together to collaborate in the field of leukemia. As an initial exercise to establish denominators a retrospective data analysis was undertaken (Indian acute leukemia research database [INwARD]). Here we present the retrospective analysis of the acute lymphoblastic leukemia (ALL) data.

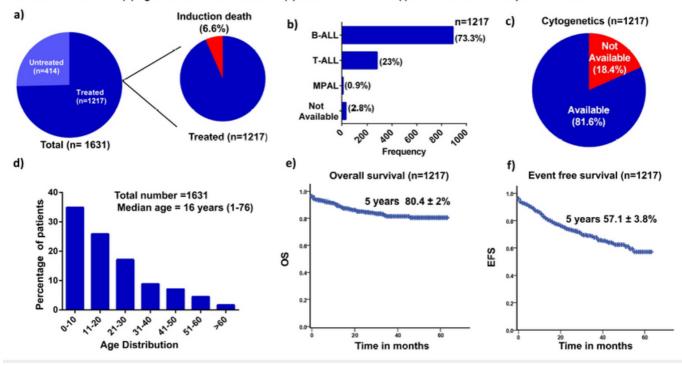
Retrospective data from January 2013 to December 2017 was collected from 7 large tertiary centers from across the country. A central online data capture and management system was in place which was independent of all the participating centers (Clinical Data Management Center [CDMC], Vellore, which is compliant with standard ICH-GCP regulations). In this initial phase some centers contributed data offline to the data management center. A total of 1631 patients were confirmed to have had a diagnosis of ALL in this period of which it was noted that 1217 (75%) received definitive treatment (Fig 1 a). The majority of treated cases were B ALL (73%) followed by T ALL (23%), MPAL was diagnosed in 11 cases (0.9%) (Fig 1b). Of the 1217 patients that received treatment a karyotype report was available in 81.6% (Fig 1c), while FISH/PCR data was available in 703 (58%) of cases. The median age of the patients was 16 years (range: 1-76) and there were 70% males. The age distribution of patients by each decade is illustrated in Fig 1d. Of the diagnosed cases 879 (54%) were \leq 18 years of age. Following initial induction therapy 80% of patients achieved complete hematological remission (CR) and there were 6.6% induction deaths. Only 37 (3%) received an allogeneic SCT in CR1. The 5 year KM estimate for overall and event free survival for the entire cohort of patients that received treatment was $80.4\pm2\%$ and $57.1\pm3.8\%$ respectively.

This retrospective data gives a snapshot of the status of treatment of ALL in India and illustrates the challenges. A significant proportion of cases due to various constraints abandon therapy and a significant proportion of treated cases do not have conventional karyotyping or molecular tests done prior to start of therapy which would be considered a deviation from the standard of care in the developed world. This collaborative group has the potential to evaluate and understand these challenges in greater depth over subsequent prospective studies and develop strategies to overcome them.



ABSTRACT ID#: 1374

Figure 1: (a) Illustrate the proportion of patients treated of those diagnosed and also the proportion of those treated that had an induction death (B) Proportion of different sub-types of ALL. (c) Illustrates the proportion of cases where a karyotype was available among the patients that received treatment (d) Age distribution of this cohort (e) Overall survival and (f) Event free survival of patients treated.





Abstract ID#: 4006 Hematological Cancer Consortium: Multi-Center Acute Myeloid Leukemia Registry Data from India

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ABSTRACT ID#: 4006

Multicenter large collaborative research groups have been the cornerstone for advances that have been made in multiple disciplines in medicine. These collaborative groups are specifically useful in situation where no single center based dataset is large enough to effectively address biological and clinical relevant questions that could advance the field. Most such collaborative groups exist in the developed countries and have contributed significantly to the development of the current standards of care in leukemia. The challenges in the developing countries or low middle income countries (LMIC) are distinctly different and often algorithms that have evolved in the developed world may not be applicable, relevant or accessible in the LMIC. It is imperative that these challenges be addressed through large multicenter studies that are located within the LMIC and appropriate local data driven solutions be implemented in response. The 'Hematological Cancer Consortium' is a collaborative group from India currently compromising twelve institutions spread across the country that have come together to collaborate in the field of leukemia. As an initial exercise, to establish denominators a retrospective data analysis was undertaken (Indian acute leukemia research database [INWARD]). Here we present the retrospective analysis of the acute myeloid leukemia (AML) data.

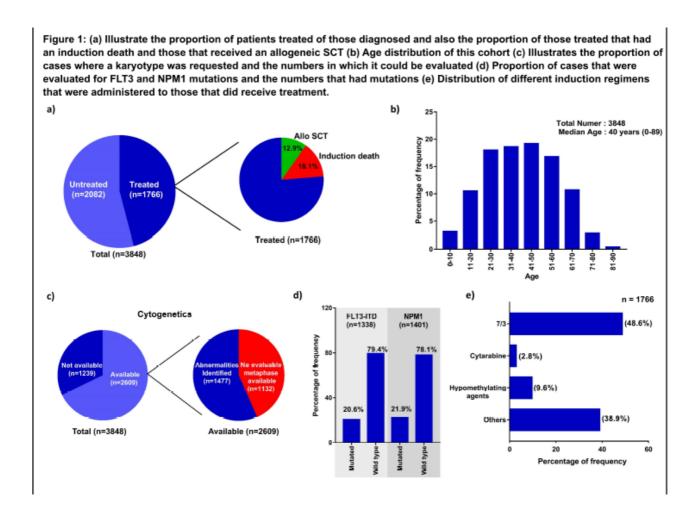
Retrospective data from January 2013 to December 2017 was collected from 10 large tertiary centers from across the country (in one center data was available only from January 2017). A central online data capture and management system was in place which was independent of all the participating centers (Clinical Data Management Center [CDMC], Vellore, which is compliant with standard ICH-GCP regulations). In this initial phase some centers contributed data offline to the data management center. A total of 3848 were confirmed to have had a diagnosis of AML in this period of which it was noted that 1766 (46%) received definitive treatment (Fig 1 a). The median age of the patients was 40 years (range: 0-89) and there were 59% males. The age distribution of patients by each decade is illustrated in Fig 1b. 399 (10.4%) were ≤ 18 years). A sample for karyotyping was sent in 2609 (68%) however of these an evaluable karyotype was noted in only 1477 (57%) (Fig 1c), the reasons for lack of evaluable metaphases was not clear. A FLT3 and NPM1 mutation status was evaluated in 1338 (35%) and 1401 (36%) respectively. Of the evaluated patients 20.6% and 21.9% had FLT3-ITD and NPM1 mutated respectively (Fig 1d). Of the 1766 patients that were treated 858 (48.6%) received a conventional 7/3 induction, 170 (9.6%) received hypomethylating agents while the rest received various abbreviated dose regimens and a small proportion (2.8%) received high dose cytosine based regimens as induction therapy. Antifungal prophylaxis was used by 82% of patients that received therapy. Of those that received induction therapy there were 18% induction deaths and 12.9% subsequently received an allogeneic SCT as part of their consolidation therapy (Fig 1a). The 5 year KM estimate for overall and event free survival for the patient that received treatment was 56.2±2.6% and 33.8±2.4% respectively.

The data illustrates significant challenges and opportunities with the management of AML in India. A significant proportion of cases do not receive definitive therapy nor do they have conventional tests such as karyotyping or molecular tests done as part of the baseline diagnostic tests, various social and financial



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constraints could contribute to these and these need to be evaluated in more detail. Strategies to increase access to care and laboratory facilities along with an effort to reduce early induction deaths need relatively urgent attention. The relatively young age of the cohort and large number of cases would allow us to address relevant biological and clinically challenges effectively, in the future, in this cooperative setting.





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