Hematology Cancer Consortium

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in collaboration with the Research and Education Society of Medical Oncology (RESMO)

Evidence-based and Context- driven Best practices for Treatment of Hematological Cancers

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Venue: NCI-AIIMS, Jhajjar

ABSTRACT BOOKLET

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Paper No: 1

Real World Outcomes With The Use Of Inotuzumab Ozogamicin In Relapsed /Refractory B-Cell Acute Lymphoblastic Leukemia

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Introduction:
There is paucity of real-world data on the use of Inotuzumab Ozogamicin (InO) in patients with relapsed/refractory B-acute lymphoblastic leukemia (R/R B-ALL).

Aims:
To study the real-world clinical outcomes in patients with R/R B-ALL who have received InO as salvage chemotherapy.

Methods:
Hospital records were used to retrieve data of patients with R/R B-ALL at our institution from January 2020 to December 2024. Data cut-off date was 1st March 2025.

Results:
During the study period, 127 patients were diagnosed with relapsed/refractory B-ALL (R/R B-ALL). Of these, 52 (including 2 treated elsewhere) received InO for refractory (n=12) or relapsed (n=40) disease; 7 were Ph+. The median age was 23.5 years (range 6–68). Forty-seven (90.3%) received chemotherapy prior to InO, and 7 had undergone prior HSCT. A median of 3 doses of InO (range 1–12) were used as 1st/2nd (n=26) or 3rd/later (n=26) salvage. Five patients died before response assessment; 25 achieved complete remission (CR), including 20 who were MRD-negative. Following CR, 20 patients (42.5%)—3 of whom were MRD-positive pre-transplant— underwent HSCT (median 45 days post-InO), 3 (6.38%) received DLI (post-transplant relapse), and 2 (4.25%) underwent CAR-T therapy (one followed by HSCT). One-year event-free survival (EFS) was 38.5% ± 7.9% overall, and 51.3% ± 11% among transplant recipients, with 5 (25%) non-relapse deaths and 7 (35%) relapses.

Seventeen patients (32.6%) were hospitalized for febrile neutropenia. Thirteen (25%) developed VOD, 12 of whom had undergone HSCT. Median follow-up for survivors was 10.5 months. At last follow-up, 29 patients (14 post-HSCT) were alive. Deaths were due to disease progression (11), infection (5), and intracranial bleed (1); post- HSCT deaths included progression (1), infections (3), VOD with infection (1), and cerebrovascular accident (1).

Conclusion:
InO offers remission in ~50% of R/R B-ALL patients, enabling consolidation with HSCT or cell therapy, but relapse and post-transplant complications remain key challenges.

TABLE 1 – BASELINE PATIENT CHARACTERISTICS AND OUTCOMES

CHARACTERISTICS	NUMBER (%) OR MEDIAN (RANGE)
Total number of patients	52
Age (in years)	23.5 (6-68)
Male sex	41 (78.8%)
Disease type 1. Primary refractory disease 2. Very early/early relapse 3. Late relapse 4. Post-transplant relapse	 12 (23.07%) 24 (46.15%) 9 (17.3%) 7 (13.46%) (1 CR1, 5 CR2 and 1 CR3 transplants)
Disease status prior to InO 1. Morphologic disease 2. Morphological remission with positive MRD	 49 3
Extent of disease prior to InO 1. Peripheral blood WBC count 2. Proportion of peripheral blasts on morphology 3. Proportion of marrow blasts on morphology 4. CNS disease	 4200 per cu.mm (Range: 600-77,500) 0 (0-92%) 40 (0-95%) 6 (11.5%)
Pattern of InO use 1. Single agent InO 2. Single agent InO with triple intrathecal 3. Along with chemotherapy	 46 (88.4%) 2 (3.84%) 4 (2–Mini-HYPER CVAD, 2–dasatinib) (7.69%)
Median number of doses of InO used Median number of doses of InO used among responders	3(range 1-12) 3(range 2-12)
Line of salvage of InO 1. First line 2. Second line 3. Third or later	 5 (9.61%) 21 (40.38%) 26 (50%)
Response to salvage InO Morphologic disease (n=49) 1. Not assessed 2. Remission 3. No response Remission with MRD positivity (n=3)	 5 (9.61%) 28 (53.85) (of which 20 were MRD negative) 16 (30.7%) (MEDIAN DOSES OF InO – 3 [2-9]) All patients had MRD response (2 became MRD negative after 1 cycle; second had reduction of MRD from 1.4 to 0.06 after 2 cycles)
Subsequent therapies 1. Following response (n=31)	 Allogeneic HSCT (n=20), DLI (n=3), CAR-T (n=2),
2. Following non-response (n=16)	Others (n=6; 1-BFM REZ Protocol; 2 – Awaiting HSCT; 1 – CART elsewhere,1 – sepsis with encephalopathy – Palliation, 1 – Continue InO at local place) Intensive chemotherapy (n=4), Palliation (n=11), DLI (n=1)
Status of last follow-up 1. Alive	 29 (55.7%)

2. Death due to progressive disease 3. Death while in remission 4. Post-transplant death	11 (47.8%) 6 (26.08%) (Sepsis (5) and intracranial bleed (1)) 6 (26.08%)
Median follow-up of the entire cohort from initiation of InO	6 months (Range 1-41)
Median follow-up of the surviving patients	10.5 months (Range 2-24)

Paper No: 2

R-CHOP Versus R-DAEPOCH for Patients with Newly Diagnosed Double-Expressor Lymphoma

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Background: Double-expressor lymphoma (DEL) is a highly aggressive subtype of Diffuse Large B cell lymphoma and is often managed with intensified treatment protocols. The impact of treatment intensification on outcomes remains unclear.

Methods:
This retrospective study analyzes outcomes in patients with DEL treated with either R-CHOP or R-DAEPOCH between January 2016 and October 2023. 245 patients were diagnosed with DEL of which 118 initiated chemotherapy at our institution - 75 received R-CHOP, and 43 received R-DAEPOCH. The median age at diagnosis was 50 years (Range 18-80), and 69.5% were male. Of the 110 patients for whom cell-of-origin data was available based on Han's algorithm, 67.3% (51/63 R-CHOP and 23/37 R-DAEPOCH) were of the non-GCB subtype. 48/118 (40.7%) had stage IV disease, and 28/118 (23.7%) of the patients had bulk disease. (**Table 1**)

The median follow-up duration was 401 days (Range 6 -2279). End-of-therapy (EOT) data was available for 95 patients (59 R-CHOP and 36 R-DAEPOCH). CR rates were 78% and 72.2% (p = 0.649) and ORR rates were 88.2% and 83.3% (p= 0.404) in R-CHOP and R-DAEPOCH arms, respectively. Nine out of 10 patients in PR at EOT (5 RCHOP and 4 R-DAPEOCH) were given IFRT (36-45 Gy). There was no difference in the two-year PFS (72.7 +/- 5.7months and 63.7 +/-8.1 months, p=0.430) between R-CHOP and R-DAEPOCH, respectively. 13 patients had primary progressive disease while 13 patients have relapsed at a median of 5 months. (**Table 2**)

Although admissions for febrile neutropenia were comparable [1 (0-3) for R-CHOP and 2 (0-5) for R-DAEPOCH] (p=0.185) between both groups, patients who received R-DAEPOCH experienced a significantly higher incidence of documented infectious complications (p=0.007).

Conclusion:
This retrospective analysis did not support treatment intensification with R-DAEPOCH over R-CHOP for Double-expressor lymphoma.

Table 1 Baseline Characteristics

	Total n=118, n (%)/ Median (Range) /Mean ± SD	R CHOP n= 75, n (%)/Median (Range)/ Mean ± SD	R DA Epoch n=43, n (%)/Median (Range)/ Mean ± SD
Median Age	50 (18-80)	52 (18-80)	47 (19-68)
Male Sex	82 (69.5%)	52 (69.3%)	30 (69.8%)
HIV Positive	4 (3.3%)	3 (4.0%)	1 (2.3%)
Cell of origin **GCB** **Non-GCB**	N = 110 36 (32.7%) 74 (67.3%)	N =73 22 (30.1%) 51 (69.9%)	N =37 14 (37.8%) 23 (62.2%)
Ann Arbor stage **I** **II** **III** **IV**	 14 (11.9%) 28 (23.7%) 28 (23.7%) 48 (40.7%)	 11 (14.7%) 18 (24.0%) 18 (24.0%) 28 (37.3%)	 3 (7.0%) 10 (23.3%) 10 (23.3%) 20 (46.4%)
Extra Nodal Disease	36 (30.5%)	20 (26.7%)	16 (37.2%)
Bulk Disease	28 (23.7%)	20 (26.7%)	8 (18.6%)
Median LDH	548 (174-7430)	536 (174-7430)	548 (178-3917)
Median IPI	2 (0-5)	2 (0-5)	2 (0-4)
IT MTX	31 (26.3%)	17 (22.7%)	14 (32.6%)

Table 2 – Outcomes

	Total (n=118) n (%)/ Median (Range) /Mean ± SD	**R-CHOP (n= 75) n (%)/ Median (Range)/Mean ± SD**	**R-DA-EPOCH(n=43) n (%) Median (Range)/Mean ± SD**	**P value**
Febrile Neutropenia Admissions	1 (0-5)	1 (0-3)	2 (0-5)	0.185
Infectious Complications	34 (28.8%)	15 (20.0%)	19 (44.2%)	0.007
Median Cultures drawn	3 (0-23)	2 (0-17)	6 (0-23)	0.000
Interim Response	**N=96**	**N=61**	**N=35**	**0.404**
CR	23 (24.0%)	17 (27.9%)	6 (17.1%)	
PR	65 (67.7%)	40 (65.6%)	25 (71.4%)	
PD	8 (8.3%)	4 (6.6%)	4 (11.4%)	
EOT response	**N=95**	**N=59**	**N=36**	**0.649**
CR	72 (75.8%)	46 (78.0%)	26 (72.2%)	
PR	10 (10.5%)	6 (10.2%)	4 (11.1%)	
PD	13 (13.7%)	7 (11.9%)	6 (16.6%)	
Relapse	11 (9.3%)	6 (8.0%)	5 (11.6%)	0.526
Radiotherapy	25 (21.2%)	15 (20.0%)	10 (23.3%)	0.815
Transplant	2 (1.7%)	0 (0%)	2 (4.7%)	0.131
Death	5 (4.2%)	4 (5.3%)	1 (2.3%)	0.709
Status at last follow up	**N =99**	**N =62**	**N =37**	**0.306**
CR	70 (70.7%)	46 (74.1%)	24 (64.8%)	
PR	3 (3.0%)	2 (3.2%)	1 (2.7%)	
PD	26 (26.3%)	14 (22.6%)	12 (32.4%)	
1-year PFS 2-year PFS (Months)	71.9 +/- 4.5 69.5 +/- 4.7	74.6 +/- 5.5 72.7 +/- 5.7	66.9 +/- 7.9 63.7 +/-8.1	0.430

Figure 1 Consort Figure

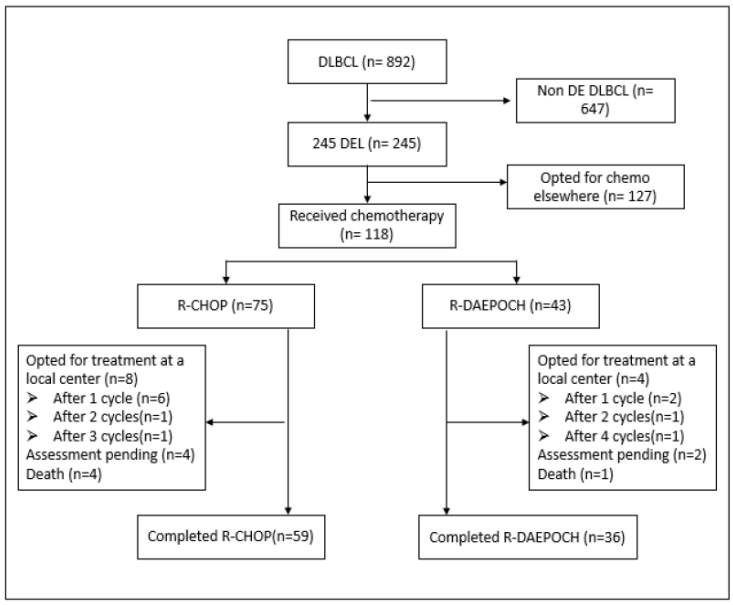


Figure 2 Alluvial plot of the entire patient cohort

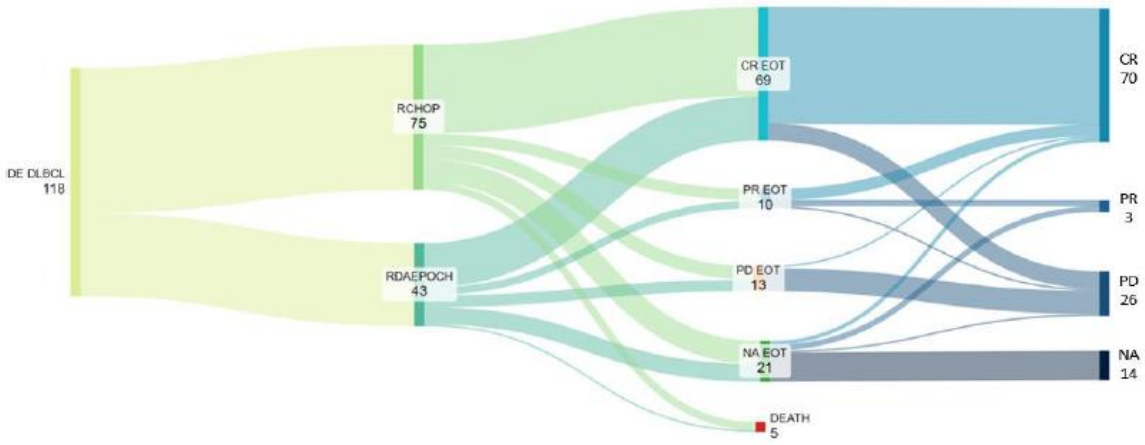
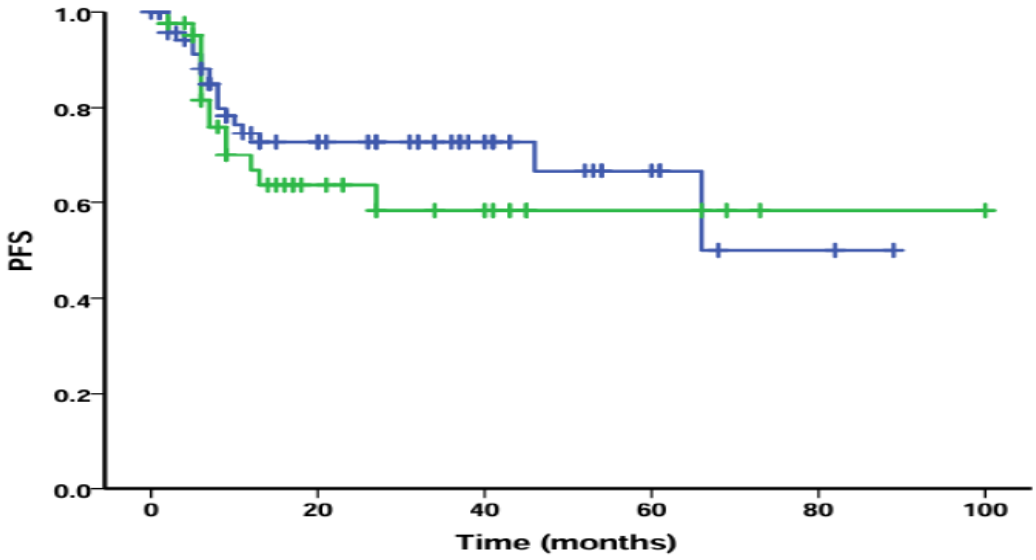


Figure 3 Progression Free Survival (PFS) of all DEL patients.



Paper No: 3

Safety and Feasibility of Outpatient Induction Chemotherapy in Adolescent and Adult AML: A Single-centre Pilot Study

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Authors: Dr. Hasmukh Jain, Dr. Thomas Eipe, Dr. Manju Sengar, Dr. Alok Shetty, Dr. Lingaraj Nayak, Dr, Bhausaheb Bagal, Mangesh Kadam, Dr. Neha Sharma
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Background:
Delayed initiation of treatment in AML patients often lead to detrimental outcomes (Juliusson G, Blood Adv 2021). In our high-volume centre there is an average three-week delay in treatment initiation reflecting the substantial burden in resource-constrained settings (Jain H, JGO 2020).To overcome this problem, our study aimed to study the safety and feasibility of an outpatient induction model in our setting.

Methods:
This is a single-centre, open-label, pilot study conducted from March 2021 to May 2023. Newly diagnosed AML patients aged 15-65 years, ECOG PS≤1, total leukocyte count<20,000cells/mm3, with no active infection and bleedingwere enrolled either before induction or on Day 9-10. All patients received standard 7+3 (Daunorubicin/Idarubicin and Cytarabine)induction. The primary endpoint was 28-day induction mortality.

Results:
A total of 30 patients were enrolled, 20 before induction and 10 after day 8. The median age was 25 years (15–46), with females representing 37%. One patient died during induction (day 11) from COVID-19 infection. Complete remission was achieved in 47% after induction. Febrile neutropenia occurred in 93%, bloodstream infections in 20%, and invasive fungal infections in 27% (probable in 2, possible in 6). At 40 months' median follow-up, 2-year progression-free and overall survival was37% and 43%. Median hospital stay was 15 days (range 0-26), time to treatment initiation 4.5 days (range 0-23), with no ICU admissions and 2 patients requiring inotropes.

Conclusion:
Outpatient induction model was feasible, reduced time to treatment initiation and did not increase induction mortality.

Paper No: 4

Short-Course Pomalidomide for Maintaining Treatment-Free Remission after TKI Discontinuation: Early Results of an Ongoing Phase II Trial

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Introduction:
Tyrosine kinase inhibitors (TKIs) have transformed outcomes in chronic myeloid leukemia in chronic phase (CML-CP). However, increasing evidence supports treatment discontinuation in patients achieving sustained deep molecular remission. Immunological mechanisms, particularly enhanced T-cell and NK-cell activity, support durable remission, and can be augmented by pomalidomide. We hypothesize that in eligible patients, short-course pomalidomide may reduce molecular relapse and improve relapse-free survival.

Methods:
Adult patients (≥18 years) with CML-CP receiving TKIs for ≥3 years, sustained MR4 for ≥2 years, with no warning/failure beyond 6 months of TKI initiation were eligible. In intervention phase, imatinib dose was reduced to 200 mg for one month in combination with pomalidomide, followed by discontinuation. Pomalidomide 2 mg was administered orally on alternate days (D1–21 of each 28-day cycle) for six months. The primary objective was 12-month molecular relapse-free survival.

Results:
This Phase II study (CTRI/2020/10/028549), initiated in May 2022 at Tata Memorial Hospital, enrolled 107 of the planned 110 patients; early results from 58 patients are presented. Median age was 40.5 years (20–64), with 69% male. Molecular relapse occurred in 30 patients (52%) within 12 months of TKI discontinuation; all were re-started on imatinib and regained MMR, with 28 achieving MR4.0. Three patients were withdrawn due to adverse events (gr3 myalgia, gr3 skin rash and gr4 myocardial infarction). No thrombotic events, or deaths were reported.

Conclusions: Pomalidomide 2 mg on alternate days was safe and did not induce TKI withdrawal syndrome. Final analysis will establish its role in maintaining treatment-free remission.

Paper No: 5

Venous thrombosis in Myeloma- Actual incidence versus predicted by IMPEDE VTE score

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Background
The predicted 6-month cumulative incidences of VTE in newly diagnosed MM(NDMM) as per IMPEDE VTE score risk category are 5.0% in the low risk group, 12.6% in the intermediate and 24.1% in high risk groups. This study was to compare the actual incidence of thrombosis versus the predicted one using IMPEDE VTE score.

Methods
A retrospective study was conducted in patients with NDMM ≥18 years of age. Incidence of thrombosis was derived at by cumulative incidence function.

Results
Among a total of 492 cases, with a median age of 62 years, ECOG PS was ≤ 2 in 372 (76%) cases. Two hundred and fifty eight cases (52 %) had co-morbidities. Aspirin was used as thrombo-prophylaxis in 336 (68%), and LMWH in 4 (0.8%) of cases. By the IMPEDE VTE score calculation 455 (92%) of cases were low risk, 37(8%) were intermediate risk, and none were of high risk category. Venous thrombosis was documented in 11 (2.2%) cases during entire follow up. The cumulative incidence of thrombosis at 6 months was 1.4 %. The cumulative incidence for low risk group and intermediate risk groups at 6 months were 1.3 % and 2.7 % respectively

Conclusion
Overall incidence of venous thrombosis in NDMM cases were very low. This holds true even when patients are categorized into various risk groups as per IMPEDE VTE score. Thrombo-prophylactic strategies may be derived at by region specific research in this situation.

Paper No: 6

Achieving Treatment Free Remission In Chronic Myeloid Leukemia: Clinical Outcomes And Challenges

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Objective:
In the current era, achieving treatment-free remission (TFR) has emerged as a key therapeutic objective in the management of newly diagnosed chronic-phase CML. This paradigm shift in treatment aims to improve quality of life and healthcare resource utilisation, reducing psychological and financial morbidity. Understanding the outcomes, challenges, and compliance patterns of TFR in real world populations, is essential for optimizing and the expanding the feasibility of this approach.

Methods:
This retrospective single-center study evaluated chronic-phase CML patients treated between May- 2019 to December-2024, who attempted TFR after a sustained deep molecular response (DMR; BCR-ABL ≤ 0.01% IS). Eligible individuals had discontinued tyrosine kinase inhibitor (TKI) therapy electively. Data included demographics, baseline ELTS risk scores, TKI type, duration of DMR, molecular relapse (loss of MMR; BCR-ABL ≤ 0.1% IS), time to relapse, and time to regain MMR after resumption of TKI. We also recorded the pattern of relapse, compliance issues. Patients were considered compliant if they underwent atleast five PCR tests during the first year after TKI discontinuation, conducted at intervals of no more than two months for the first six months, with subsequent monitoring every six months thereafter.

Results:
A total of 57 patients were included, of whom 31(54.4%) were male. The median age at diagnosis was 36 years (range, 19-63). Fifty-five (96.4%) were in chronic phase CML at diagnosis. ELTS risk scores at baseline were low in 33 (57.9%), intermediate in 13 (22.8%), and high in 11 (19.3%) patients. TFR was initiated electively in 31 (54.4%) following counselling, while 17 (29.8%) discontinued TKI due to renal injury. The median duration of TKI exposure prior to discontinuation was 13 years (range, 5-18), with a median DMR duration of 10 years (1-16). At the time of analysis, 44 patients (77.1%) remained treatment-free, 10 (17.5%) had restarted TKIs due to molecular relapse, 1(1.7%) restarted TKI due to severe myalgias post discontinuation and 2 (3.5%) had died from causes other than CML. Among those with relapse, the median time to relapse was 5 months (range, 1.5-33), with 6 relapsing in the first six months and 8 in the first year after discontinuation. No patient experienced progression to accelerated or blast phase. Following TKI resumption, the median time to MMR was 3 months (range,1.5-12). Eighteen patients (31.6%) were non-complaint with the recommended molecular monitoring schedule. At the last follow up, 29 patients were in MR4.5, 20 (35.1%) in MR4 and 6 (10.5%) in MR3.

Conclusion:

A substantial 77% of patients sustained treatment-free remission with no progression to advanced disease phases. Relapses clustered predominantly within the first six months post-discontinuation, highlighting the critical window for intensive molecular monitoring. Despite real-world challenges, our cohort reflects success of TFR.

Paper No: 7

Real-World Outcomes of interim PET positive classic Hodgkin's lymphoma (cHL). An unmet need

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Background
Interim PET positivity (Deauville score [DS] 4–5 after 2 cycles iPET2) is a strong predictor of survival in advanced Hodgkin's lymphoma (aHL). EFS with ABVD alone is 20%, while escalation (BEACOPP or autologous transplant) may improve survival to 50–70%, but real-world data is limited.

Methods
We analyzed newly diagnosed aHL patients (Jan 2019–Aug 2024) with iPET2 positivity.. Fit patients received six cycles of outpatient BEACOPP-14. Baseline characteristics, treatment, toxicity, and outcomes were collected. Non-achievement of complete response (DS 4–5 at end of therapy) or relapse were defined as events. EFS and overall survival (OS) were estimated using the Kaplan–Meier method.

Results
Of the 300 patients with aHL (stage IIB, III, and IV) identified, 25 (8.3%) had positive iPET2. Of these, 20 escalated treatment [16 (64%): BEACOPP-14, 4 (16%): Nivo-EACOPP/Nivo-AVD] while 5(20%) continued on ABVD. Of those who received BEACOPP-14 / Nivo-EACOPP (N=20), 12 (60%) patients had G-III/IV toxicity. At end of therapy, 8 (40%) patients achieved complete response, 5 (25%) had partial response, and 7 (36.8%) had progressive disease. With a median follow-up of 32 months, there were 16 events [1 year, 2 year & 3 year PFS were 68%, 56% & 36%, respectively] and 3 deaths [3-year OS:92%]. Fourteen patients (56%) received salvage chemotherapy and 8 (32%) patients proceeded to autologous stem cell transplant.

Conclusion
This first Indian real-world study shows outpatient BEACOPP-14 is feasible with manageable toxicity, yet many iPET-positive cHL patients required salvage therapy and transplant, highlighting their poor prognosis and the need for better strategies.

Paper No: 8

Clinical Spectrum and Outcomes of Rosai–Dorfman Disease: A Single-Centre Experience from India

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Background

Rosai–Dorfman disease (RDD) is a rare, non-Langerhans cell histiocytic disorder with variable clinical behavior. Data from India is scarce, and treatment strategies remain heterogeneous

Materials and Methods

We retrospectively reviewed 25 patients with histologically confirmed RDD treated between 2013–2025. Demographics, presentation, treatment, responses and follow-up outcomes were analyzed.

Results

The median age was 34 years (range 4–73); 17 (68%) were male. Common presentations were cervical lymphadenopathy (7), cutaneous/subcutaneous swelling (6), and nasal obstruction (4). (Refer Figure 1) Median duration of symptoms prior to presentation was 12 months (range 3–72). B symptoms were reported in 4 patients.

Disease distribution was isolated nodal in 5, isolated extranodal in 10 (5 had isolated cutaneous involvement), and combined nodal and extranodal in 10. Common extranodal sites included skin (7), sinonasal tract (6), bone (5), CNS (3), and orbit (3). (Refer Figure 2) The median number of extranodal sites involved was 1.5 (range 1–4). The baseline characteristics are summarized in Table 1.

First-line therapy included prednisolone (13), excision (4), observation (2), vinblastine-prednisolone (1), rituximab with excision (1), radiotherapy (1), R-CHOP (1), methotrexate (1), and sirolimus (1). Median duration of follow up was 25 months (1- 109). Responses to first-line were CR in 7, PR in 7, SD in 2, PD in 6, and NA in 3. (Refer Table 2). Of the 13 patients who received steroids. 8 subsequently went on to require second line therapy. The median time to next treatment across all therapies was 13 months (range 1–68). Patients with isolated cutaneous disease had the best response with a 80% (4/5) overall response to first line therapy. One patient died due to transformation to histiocytic sarcoma

Conclusion

RDD shows heterogeneous presentations and relapsing–remitting outcomes. For localized disease, excision and targeted approaches offer good control. Though steroids offer good control initially, two thirds subsequently require other lines of therapy for disease control.

Table 1. Baseline parameters

	Total n=, n (%)/ Median (Range) /Mean ± SD
Median Age (years)	34 (4-73)
Male	17 (68%)
Median time from symptom onset to diagnosis (months)	12 (3-72)
Presenting Complaint Cervical lymphadenopathy Cutaneous and subcutaneous masses Nasal obstruction Generalized lymphadenopathy Others	 7 (28%) 6 (24%) 5 (20%) 2 (8%) 5 (20%)
B Symptoms	4 (16%)
Type of Disease Nodal Extra Nodal Combined	 5 (20%) 10(40%) 10(40%)
Number of Extra nodal sites involved 1 2 3 4	 10 (40%) 6 (24%) 2 (8%) 2 (8%)
Extra nodal site of involvement Skin Sinonasal Bone Upper Respiratory tract CNS Orbital Liver Breast Others	 7 (28%) 6 (24%) 5 (20%) 4 (16%) 3 (12%) 3 (12%) 2 (8%) 2 (8%) 5 (20%)
Median number of biopsies for diagnosis	1 (1-4)
Median duration of follow up (months)	25 (1- 109)
Lost to follow up	3 (12%)
Death	1 (4%)

Table 2. Treatment Characteristics and Outcomes

Treatment	1st Line	CR	PR	ORR	2nd Line	CR	PR	ORR
Prednisolone	13	3 (23%)	5 (38%)	8 (61%)	3	1(33%)	2 (66%)	3 (100%)
Excision	4	3 (75%)	1 (25%)	4 (100%)	1	-	1 (100%)	1 (100%)
Observation	2$	-	-	-				
Rituximab	1	0	0	0	1	-	1 (100%)	1 (100%)
Vinblastine/ Prednisolone	1	0	0	0				
Radiation	1	1 (100%)	0	1 (100%)	1	-	-	-
R CHOP / R CVP	1	0	1 (100%)	1 (100%)	2	0	1 (50%)	1 (50%)
Methotrexate	1	0	0	0				
Sirolimus	1	0	0	0	4*	0	2 (50%)	2 (50%)
6MP/ Methotrexate					3#	0	1	1

$ 1 patient was lost to follow up and one transformed to a histiocytic sarcoma

* 2 patients on sirolimus as second line were lost to follow up. Remaining 2 had PR

Of 3 patients who received 6MP/Methotrexate, 2 had a stable disease not requiring treatment change and one had a partial response

Figure 1:

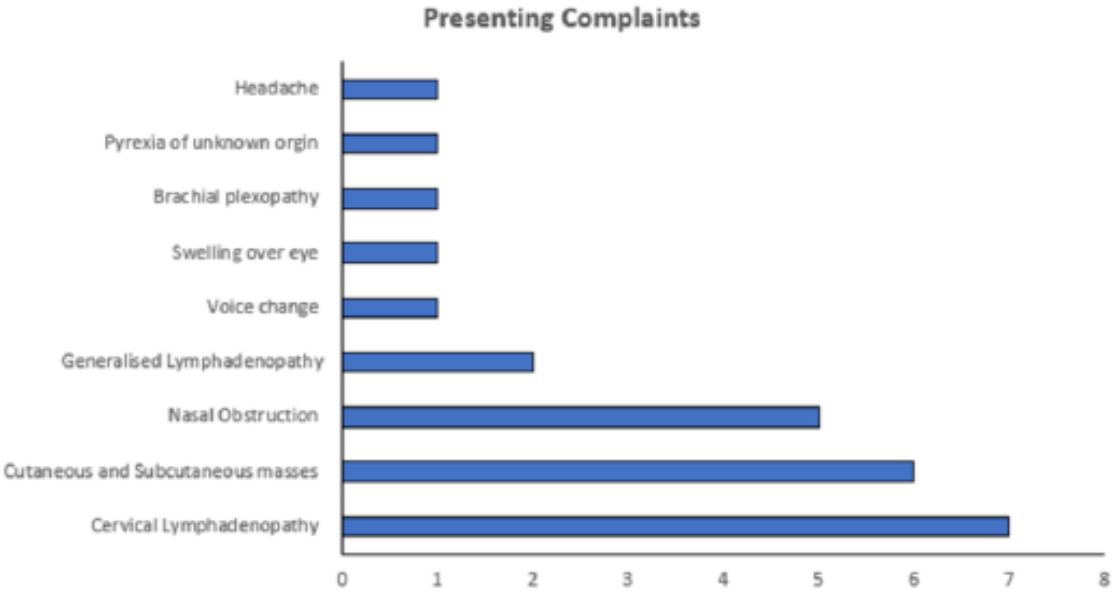
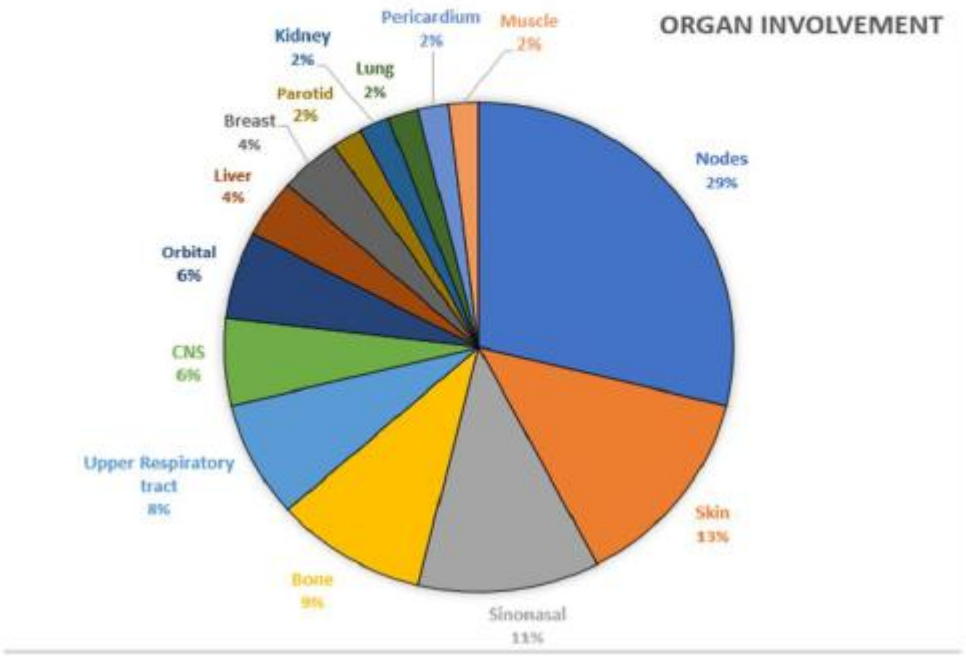


Figure 2



Paper No: 9

Single Centre Experience of Inotuzumab ozagamicin combination therapy in the frontline treatment of B acute lymphoblastic leukemia.

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Introduction
Inotuzumab ozagamicin has shown significant activity in B cell acute lymphoblastic leukemia (B ALL) with less myelosuppression than conventional chemotherapy. We present our data on the use of Inotuzumab ozagamicin (InO) in combination with less intensive chemotherapy in frontline B ALL.

Methods
A single-arm, study of adults with newly diagnosed B-cell ALL conducted at Rajiv Gandhi Cancer Institute and Research Centre, New Delhi between june 2018 to june 2025. The chemotherapy protocol consisted of mini-CVD part A (cyclophosphamide at 150mg/m2 x 4 doses, dexamethasone 20mg x 4 days, vincristine 1.5mg on day 1 and 8, but no anthracycline) or part B (methotrexate 250mg/m2 and cytarabine 0.5gm/m2 x 4 doses). InO was given at a flat dose of 1mg on day 3 of each chemotherapy arm. Rituximab 375mg/m2 was added weekly to cases that had CD20>20% expression. Central nervous system (CNS) prophylaxis included methotrexate and cytarabine alternately on day 2 and day8 of each cycle. Bone marrow evaluation with (MRD) was done on day 28 of cycle 1. The majority of patients, 23 (92%), received 1–2 cycles of therapy. Post chemotherapy maintenance consisted of prednisolone, vincristine, methotrexate and 6 mercaptopurine every 28 days for 2 years.

Results
A total of 24 patients were analysed. The median age was 30 years (range: 17–67 years), and median ECOG performance status was 1. Baseline haematological parameters showed a median haemoglobin of 9.1 g/dL (3.7-14.7), WBC count of 6,885/µL (1320-229120), and platelet count of 101000/µL (51000-745600). The median percentage of blasts was 13% in peripheral blood and 55% in bone marrow. Immunophenotyping demonstrated expression of CD19 in 19 (79%) cases, CD20 in 8(33%), and CD22 in 16 (66%). Tyrosine kinase inhibitors (TKIs) were administered in 7 (29%) patients, with ponatinib used in 2 (28.5%), dasatinib in 4 (57%), and imatinib in 1 (14%).

Complete remission (CR) was achieved in 22 (91.6%) patients, while 2 (8.3%) patients exhibited progressive disease. Minimal residual disease (MRD) negativity was achieved in 18 (75%) patients after the first cycle and was sustained in 18 (75%) during follow-up. Relapse was observed in 7 (29%) patients, with 1 mortality. At a median follow up of 68.9 months the median overall survival for the whole cohort was not reached. The estimated 2-,3- and 5- year overall survival was all 94.1% (95% CI:82.9-100).

Adverse events observed included vomiting in 2 (8%), Cytopenia in 2 (8%), neutropenia in 2 (8%), febrile neutropenia in 2 (8%), thrombocytopenia in 1 (4%), alanine transaminase (ALT) elevation in 1 (4%), and COVID-19 infection in 1 (4%). Cytogenetic evaluation revealed a normal karyotype in 22 (91%) patients, diploid in 2 (8%), and t(9;22) in 1 (4%).

Conclusion The combination of Inotuzumab ozogamicin with mini-CVD demonstrated high remission rates, deep MRD responses, and favorable tolerability in adults with newly diagnosed B-ALL, including older patients. The regimen achieved an overall survival of 95% and event-free survival of 70%, with manageable toxicity.