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**Original Research Article**

# An observational study for evaluating prescription pattern of drugs, adverse drug reactions in paediatric acute lymphoid leukaemia in a tertiary care hospital

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## ABSTRACT

**Background:** Prescription research analyses trends in prescribing drugs as per rational therapeutics principles and if any deviations found helps in providing vital feedback to physicians. Recent advances in cancer chemotherapy has improved survival rates in Acute Lymphoblastic Leukaemia (ALL), but the adverse drug reactions adds to disease burden, also compromises quality of life. There is paucity of data on prescription audit, adverse drug reactions in paediatric ALL, hence the study was planned.
**Methods:** Study was cross-sectional prospective audit. After IEC approval, written informed consent were taken from 156 prospective ALL patients aged 1-15 years (completed one cycle of induction phase). The variables assessed were WHO prescribing indicators, completeness. The details of adverse drug reactions-type, severity, preventable; causality assessment (WHO-UMC, Naranjo Scales). Analyzed by descriptive statistics [Microsoft Excelv16.0].
**Results:** Out of total 156 prescriptions (2576 drugs prescribed), total drugs per prescription was 16. Most of the drugs were prescribed by generic name (97.94%). Commonest anticancer drug prescribed in regimen was vincristine, methotrexate. Most common supportive medication class were antiemetic, antacid, antiulcer. 100% prescriptions were complete for anticancer drugs, 66% for supportive care medications. Most common ADR found was alopecia (100%), febrile neutropenia (31.41%) and fatigue (30.76%). Majority ADR were possibly (93.81%) related to treatment. 37.97% ADR were of moderate severity, 100% ADRs were not preventable.
**Conclusions:** The commonest anti-cancer drugs prescribed are vincristine, methotrexate and supportive care prescribed is antiemetic therapy (granisetron). The frequent adverse drug reaction found was alopecia, febrile neutropenia.

**Keywords:** Alopecia, Methotrexate, Paediatric ALL, Vincristine

## INTRODUCTION

Leukaemia is the most common childhood malignancy, accounting for approximately one third of cancers diagnosed in children, and acute lymphoblastic leukaemia (ALL) accounts for over three-quarters of all childhood leukemias, with the majority of these being of the precursor B-cell type. In 2017, there were an estimated 1,00,012 people living with acute lymphocytic leukaemia in the United States.[1] The incidence of childhood ALL is approximately 3-4 cases per 100,000 children under the age of 15 years in India.[2]

In tumours manifesting as "leukemias," blasts accumulating in the marrow suppress the growth of normal hematopoietic cells by physical displacement and

by other poorly understood mechanisms. Over time, this suppression results in bone marrow failure, which causes the majority of clinical symptoms. The therapeutic goal, therefore, is to reduce the leukemic clone sufficiently to allow normal hematopoiesis to resume.[3]

There are various management protocols for ALL including an induction phase with combination chemotherapy, a consolidation phase that involves administration of high-dose systemic therapy and treatment to eliminate disease in the CNS, and a maintenance therapy to prevent relapse. Childhood ALL also often serves as the paradigm for risk-based therapy, whereby stratification of treatment intensity is based on risk of treatment failure.[4]

Although there are advances in treatment of ALL, a large number of patients suffer from potentially toxic effect of drugs. Also various treatment protocols followed in different settings show variation in intensity of treatment and also results in toxicity enhancement. With the advancement of ALL therapy, there is increased risk of induction deaths related to infection, and risk of other toxicities.[5]

However, with time there have been decreasing relapses, fewer mortalities and better 5-year overall survival rates. However, this has come at the cost of adverse reactions, repeated hospitalizations and expenses due to high cost of medicines and supportive care. The out of pocket expense is immense in developing countries.

One of ways to find the present trend of prescriptions, drug availability in the hospital and costing to the patient is undertaking drug utilization studies which includes prescription research.

Prescription research does analyse the pattern of prescription, drug availability, adverse effects, cost bearing by the patients with local guidelines adherence and any deviations which can help in providing vital feedback to physicians. Prescription pattern studies are significant in these patients to capture changes in prescription due to different adverse events profiles, especially in induction phase since treatment related deaths due sepsis are highest. Even if there is no variability in tertiary care hospital where everyone follows the same protocol, there can variations in private clinics where prescriptions can be dictated by many other factors. We will be interested in knowing which are the common drugs prescribed in a tertiary care hospital for ALL and the adverse effects they cause.

Despite advances in treatment and improvement in survival rates in ALL, the adverse drug reactions add to the disease burden and also compromises the quality of life.

When the literature search was undertaken by using search term on PUBMED as “acute lymphoblastic leukaemia AND Prescription research”, we found few studies which included medication errors, drug efficacy, adverse events of single drugs and pharmacogenomic analysis of disease and treatment of ALL, but, there are no studies on prescription audit and adverse effects assessment in ALL. Hence the study was planned in this direction.

## METHODS

This was a cross-sectional, observational, prospective study for finding the prescription pattern in the induction phase of Paediatric Acute Lymphoblastic Leukaemia. Also the adverse reactions at the end of Induction phase were captured. This was a collaborative study between Seth GS Medical college Mumbai and Tata Memorial Charitable Hospital (TMCH), Mumbai. Study site was Paediatric hematoncology OPD of TMCH, Mumbai. The study was approved by Institutional Ethics Committees of both the sites (IEC approval numbers EC/Project No.: 3696 and EC/104/2020). The study was registered in the CTRI Registry (CTRI/2021/09/036279). Patients of either gender and age between 1-15 years treated with one cycle in induction phase were included. The study was conducted between January 2021 and March 2023.

The sample size of 200 was calculated as it was decided to be duration based and 156 was achieved prospectively. Patients who came to haemato-oncology OPD between 9 am to 12 pm for consultation and fulfilled the eligibility criteria, were approached by the investigator and were counselled about the study. If found eligible, a participant information sheet was provided with details of the study. Written informed consent and assent was taken from patient and parent/LAR and if both patient and parent/LAR are illiterate then from impartial witness. Demographic details like registration number, age and gender was captured. Prescriptions with one complete induction cycle (35 days) was considered as single prescription [each prescription had 14-18 encounters] and was recorded in the Case Record Form (CRF) as per the diagnosis and disease risk category. Prescribing indicators were evaluated as per WHO prescribing indicators for completeness of prescription.

Source for adverse drug reaction was patient file, patient history. Adverse drug reaction variables assessed included causality with WHO-UMC scale, severity with Modified Hartwig-Siegel scale and preventability with Modified Schumock and Thornton scale.

### *Statistical analysis*

Demographic data that were continuous (age) expressed as median and range. Categorical data (Gender) were expressed as percentage. Prescribing indicators and Adverse Drug Reaction were analyzed by descriptive statistics using Microsoft Excel v16.0, Microsoft, Redmond, Washington, US.

## RESULTS

A total of 156 paediatric ALL patients were part of the study. One hundred forty-three (91.67%) patients suffered from B-cell ALL while those having T-cell ALL were 13 (8.33%). Overall, the median age was found to be 8 years with interquartile range (Q3-Q1) of 10.3 (11.3-1) year. Out of 156, 84 (53.85%) were boys and 72 (46.15%) were girls. The risk-wise diagnostic stratification is summarized in Table 1.

**Table 1: Risk-wise diagnostic stratification of paediatric acute lymphoblastic leukaemia (ALL) patients.**

| Type of ALL | Risk wise ALL diagnosis | N (%) |
|---|---|---|
| **B-ALL (N= 143)** | Standard risk | 60 (38.46) |
| | Intermediate risk | 49 (31.41) |
| | High risk | 34 (21.79) |
| **T-ALL (N= 13)** | High risk | 13 (8.33) |

***Drugs prescribed***

*Anticancer drugs*

Out of 728, the most common anticancer drug prescribed in paediatric ALL was found to be vincristine (156), methotrexate (156) followed by prednisolone (152), pegylated asparaginase (151), daunorubicin (96), dexamethasone (8), l-asparaginase (5), and imatinib (4). The drugs are summarized in Figure 1.

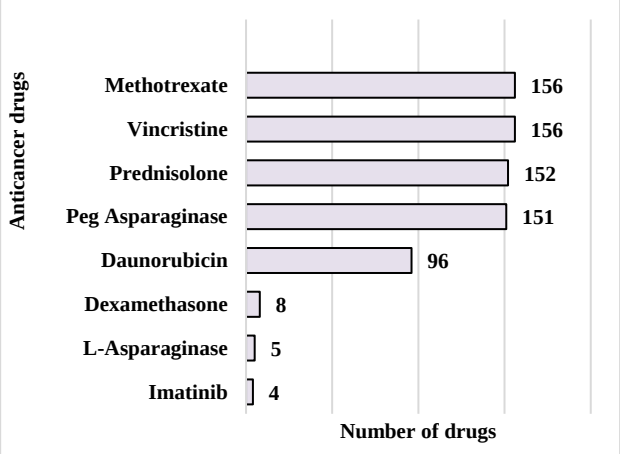


**Figure 1: Anticancer medication for induction phase of paediatric ALL.**

*Supportive care drugs*

Out of 1848 Supportive care medication, most common medications class prescribed includes antiemetics, antacids, antiulcer (290); followed by minerals and multivitamins (197). The drug class summarized in Figure 2.

*Anticancer drug regimens prescribed*

Total 5 drug regimens were found in 156 patients. 92 High risk and intermediate risk ALL (B-ALL and T-ALL) patients had prednisolone, methotrexate, vincristine, peg-asparaginase, daunorubicin prescribed. 60 Standard risk B-ALL included 3 drug regimen- a) prednisolone, vincristine, methotrexate, peg-asparaginase [47], b) pulsatile steroid, vincristine, methotrexate, peg-asparaginase [8], c) prednisolone, vincristine, methotrexate, L-asparaginase [5], 4 High risk T-ALL patients included prednisolone, vincristine, methotrexate, peg-asparaginase, daunorubicin, imatinib. Figure 3 summarizes drug regimen.

**Table 2: Prescribing indicators (n=156).**

| Prescribing indicators | | Overall value |
|---|---|---|
| **Total no. of patients** | | 156 |
| **Total no. of prescriptions *** | | 156 |
| **Total no. of encounters per patient *** | | 14-18 |
| **Total no. of drugs prescribed** | | 2576 |
| **Average number of drugs per prescription** | | 16.51±1.48 |
| **Average number of drugs per prescription for ALL standard risk** | | 15.87±0.81 |
| **Average number of drugs per prescription for ALL intermediate risk** | | 16.43±1.21 |
| **Average number of drugs per prescription for ALL high risk** | | 17.42±1.81 |
| **Number of anti-cancer drugs prescribed** | | 728 (28.26) |
| **Number of concomitant (supportive care) drugs prescribed** | | 1848 (71.74) |
| **Number of anticancer drugs risk-wise** | High risk (n=47) | 243 (33.38) |
| | Intermediate risk (n=49) | 245 (33.65) |
| | Standard risk (n=60) | 240 (32.97) |
| **Number of supportive care drugs risk-wise** | High risk (n= 47) | 576 (31.17) |
| | Intermediate risk (n=49) | 560 (30.30) |
| | Standard risk (n=60) | 712 (38.53) |
| **Drugs prescribed by generic name** | Anticancer drugs | 713 (97.94) |
| | Supportive care drugs | 758 (41.02) |
| **Drugs prescribed by brand name** | Anticancer drugs | 15 (2.06) |
| | Supportive care drugs | 1090 (58.98) |
| **Number of complete prescriptions *** | Anticancer drugs | 156 (100) |
| | Supportive care drugs | 103 (66.03) |
| **Number of incomplete prescriptions *** | Anticancer drugs | 0 (0) |
| | Supportive care drugs | 53 (33.97) |

*One complete Induction cycle (35 days) was considered as single Prescription for cycle and each prescription had 14-18 encounters

***Adverse drug reactions (ADR)***

Total number of ADRs captured during induction phase (35 days) for 156 patients were 582. Table 3 summarizes ADR distribution across 156 patients. The most common Clinico-Laboratory ADR included was febrile neutropenia (49) followed by hypertension (34). Figure 4 summarizes clinicolaboratory diagnosed ADR. Figure 5 describes type of ADR distribution.

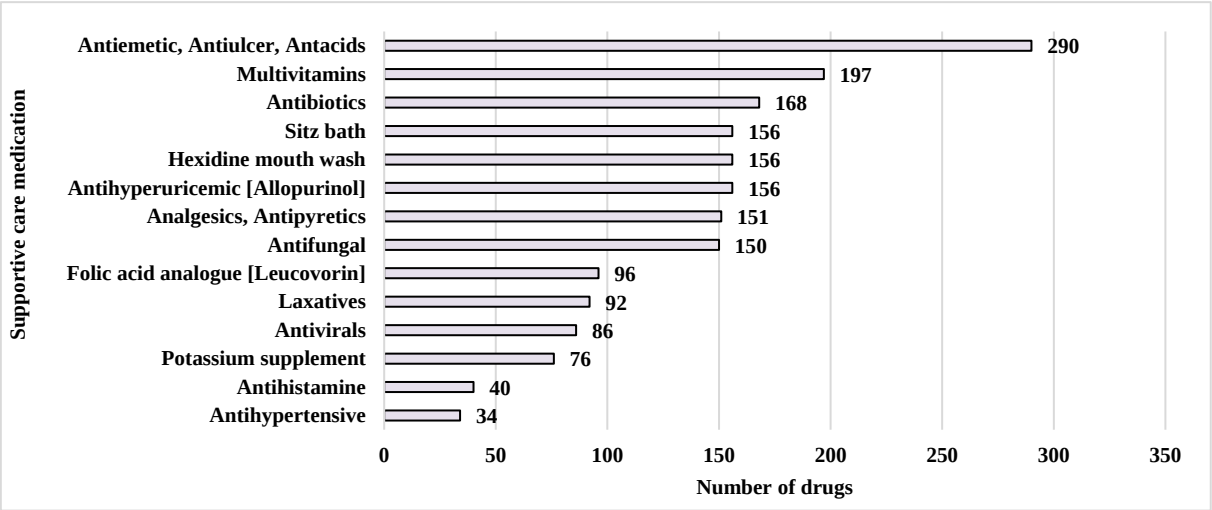


**Figure 2: Anticancer medication for induction phase of paediatric ALL.**

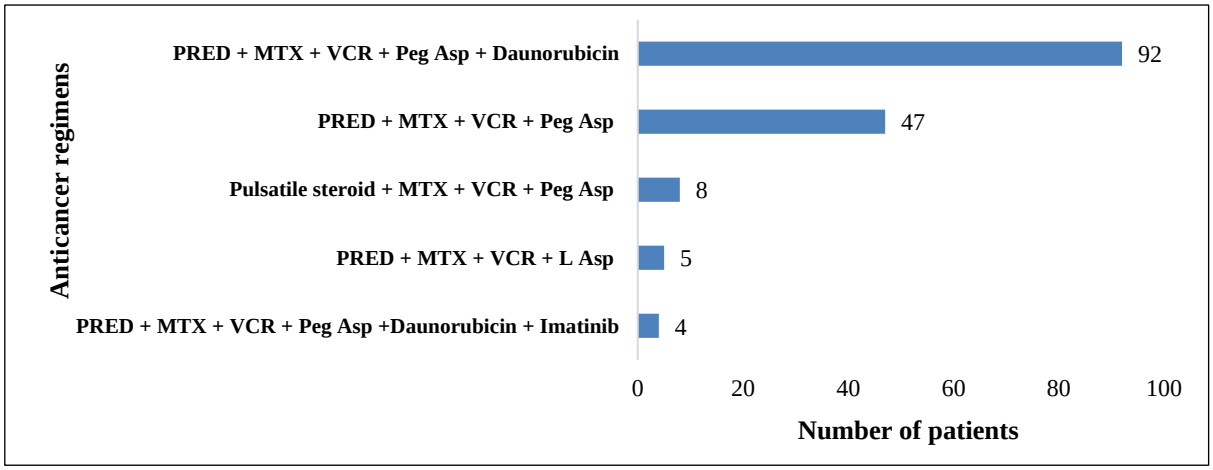


**Figure 3: Anticancer drug regimen distribution (n=156).**

Abbreviations: PRED -Prednisolone (continuous), MTX – Methotrexate, VCR- Vincristine, Peg-Asp-Pegylated Asparaginase, SR-Standard risk, IR- Intermediate risk, HR- High risk

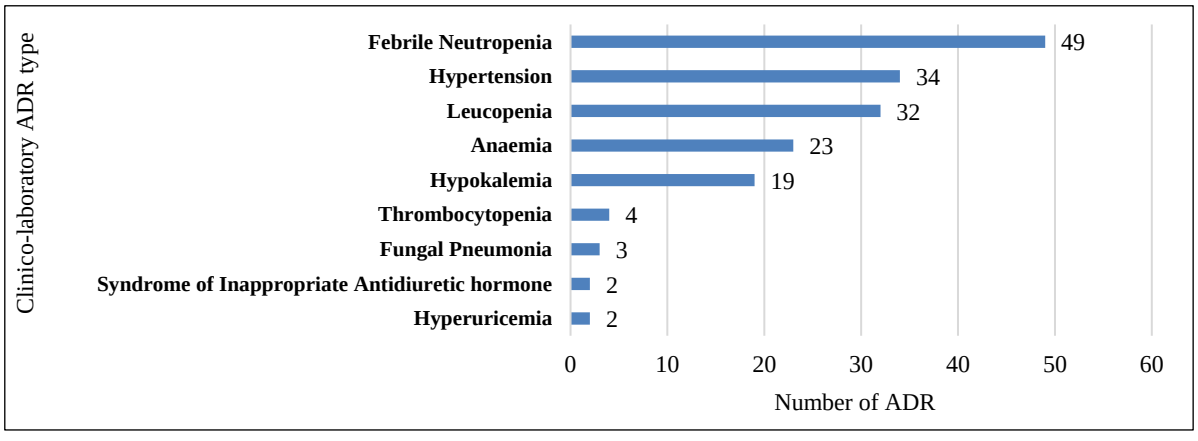


**Figure 4: Clinico-Laboratory ADR distribution (n=168).**

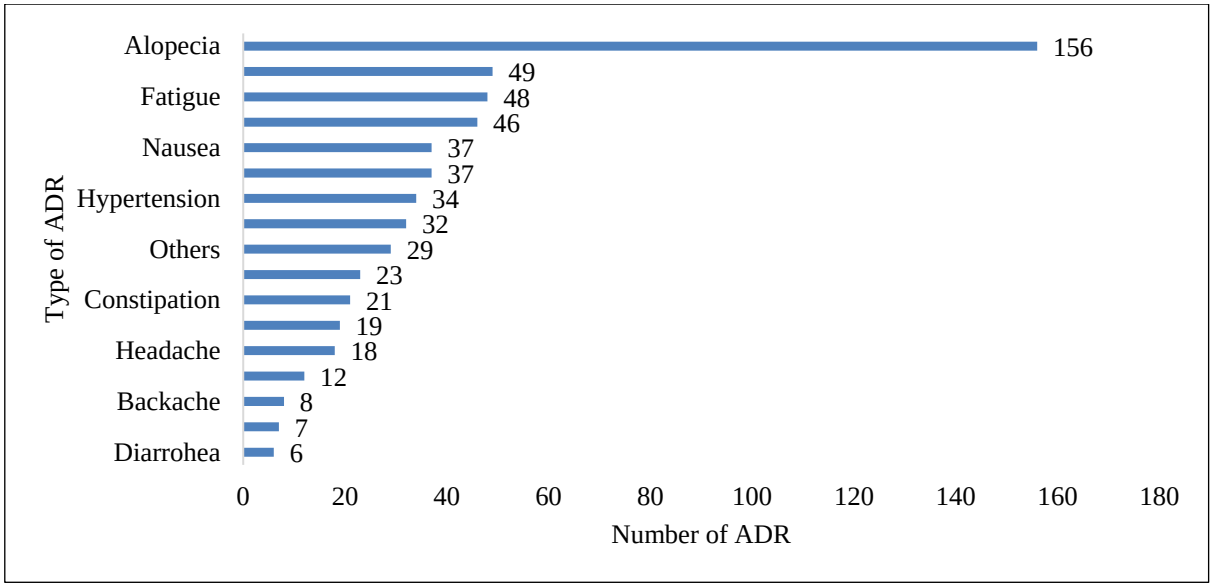


**Figure 5: Type of ADR distribution (n=582).**

**Table 3: ADR distribution.**

| ADR distribution | | Overall value (%) |
|---|---|---|
| **Total number of patients** | | 156 |
| **Total number of ADR** | | 582 |
| **Standard risk ALL (n=60)** | Total number (N=582) | 228 (39.17) |
| | Average number of ADR | 3.8±1.10 |
| **Intermediate risk ALL (n=49)** | Total number (N=582) | 174 (29.90) |
| | Average number of ADR | 3.55±1.02 |
| **High risk ALL (n=47)** | Total number (N=582) | 180 (30.93) |
| | Average number of ADR | 3.83±1.12 |
| **Number of clinico-laboratoy diagnosed ADR** | | 168 (28.86) |
| **Number of clinically diagnosed ADR** | | 414 (71.14) |

***Causality assessment of ADR***

As per the WHO UMC causality assessment scale, 582 out of the 546 (93.81%) ADRs were possibly related to the prescribed medication, while 36 (6.19%) ADRs were probably related. No ADRs were definitely related since re-challenge was not done. Total probably related ADR were 36, Table 4 mentions the ADR with suspected drugs.

As per the Naranjo Algorithm, 577 (99.14%) out of 582 ADRs were possibly related to the prescribed medication while 5 (0.8%) ADRs were probably related. For fungal pneumonia (n=3) suspect drug was prednisolone and for SIADH (n=2) suspect drug is vincristine.

***Severity assessment as per modified Hartwig-Siegel Scale***

As per the modified Hartwig-Siegel scale, majority of the ADRs, i.e.; out of the 582 ADRs, 358 (61.51%) ADRs were mild, while 221 (37.97%) ADRs were moderate and 3 (0.51%) severe ADR.

**Table 4: WHO-UMC causality assessment for probably drug related ADRs.**

| Type of ADR | Suspect drug |
|---|---|
| **Oral mucositis (n=13)** | Methotrexate |
| **Constipation (n=8)** | Vincristine |
| **Pain at injection site (n=7)** | Methotrexate |
| **Extravasation of injection site (n=3)** | Vincristine |
| **Fungal pneumonia (n=3)** | Prednisolone |
| **Syndrome of inappropriate antidiuretic hormone (n=2)** | Vincristine |

***Preventability assessment***

By Modified Schumock Thornton scale; 100% adverse drug reactions were not preventable.

## DISCUSSION

The present study evaluated the prescription pattern of drugs used for treating paediatric cancer patients in the induction phase of Acute lymphoid leukaemia (35 days) and the adverse drug reaction of drugs in a tertiary cancer care hospital.

Out of 156 patients in our study, 91.67 % were B-ALL and 13% were T-ALL. This finding is in line with Farah et al study which had 81 (93.1%) B-ALL, 6 (6.9%) T-ALL patients.[6] Zawitkowska et al study had 32.4% standard risk, 47.7% intermediate risk and 20% high risk patients.[7] Their study had maximum intermediate risk while our study had maximum standard risk patients. Overall median age was found to be 8 years which is inline with Manjesh et al study, however as per global burden disease study, incidence and prevalence of ALL is more common in 1-4 years of age.[8,1] Gender-wise distribution trends are similar to Cartwright et al, Manjesh et al and Pearce et al with boys as study patients.[8-10] The Indian cancer registries show similar data of male preponderance.[11]

Only prescribing indicators were evaluated as it is relevant for a tertiary care hospital. It can give us the general trend of prescription pattern among oncologists in that particular hospital at the end of induction phase in paediatric ALL. Although we have not evaluated patient care indicators and facility indicators as they are very relevant to primary care setup.

An average of 16 drugs were prescribed for entire induction phase across all risks, these included anticancer medication and supportive care. In the last two decades, because of remarkable progress in the chemotherapeutic treatment regimens along with supportive care adapted to local social and economic conditions which was the finding in the study which can bring expected outcomes.[12,13]

Out of total 782 anticancer drugs only 2.06% are prescribed by brand name, while 58.98% of total supportive care drugs are prescribed by brand name. Although many physicians may not regard the use of brand names as irrational practice in India, because many of these drugs are available only in brand form (it can be branded generics), but we have included this in analysis because of the advisory from the National Medical Council of India and Maharashtra medical Council to prescribe drugs in generics or generic names.[13] In Mathaiyan et al, Manjesh et al studies, brand names were used for anticancer care as well as supportive care but they did not mention the exact percentage of anticancer or supportive care with brand names.[8,13] The 2.06 % anticancer medication prescribed by brand name included Hamsyl injection (Peg Asparaginase). This drug form is available only in brand in the hospital formulary, so few of the physicians prescribed the drug in brand name and few in generic. Also on consulting the oncologists regarding prescription with brand name for supportive care which included calcimax (minerals and vitamins), clogen (clotrimazole), septran DS (sulfamethoxazole+trimethoprim) etc, the same reason of availability of these drugs in hospital as a single brand was given.

Most commonly prescribed anticancer drugs were Vincristine, Methotrexate followed by prednisolone, peg-asparaginase, daunorubicin, dexamethasone, L-asparaginase and imatinib. Vincristine was the most commonly prescribed drug in haematological malignancy in Manjesh et al study.[8] We encountered 5 different ALL treatment regimen, 3 standard risk regimen with 4 drugs, 1 for intermediate risk and high risk with 5 drugs, 1 for T-ALL high risk with 5 drugs plus imatinib. In our study, 2 types of regimen were advised with respect to corticosteroid usage for standard risk. In one regimen, continuous steroid was given, while in other pulsatile steroid is given. The pulsatile steroid therapy achieves immediate, profound anti-inflammatory effect and less toxicity along with no prolonged suppressive effect on hypothalamic pituitary axis.[14] The other regimen in standard risk included L-Asparaginase instead of Peg Asparaginase. In high risk T-ALL patient along with 5 drugs, imatinib was prescribed. Imatinib is a tyrosine kinase inhibitor given in BCR-ABL (Philadelphia chromosome mutations). A study in Spain with high risk Philadelphia chromosome positive ALL treated with imatinib with background chemotherapy had 78.7% event free survival vs 29.6% historical control.[15]

Along with anticancer medications, important classes of concomitant medications like antiemetics, antiulcer, minerals and multivitamins, analgesics, antibiotics etc. were advocated. Among the concomitant drugs which is the supportive care treatment, most common drug class prescribed were antiemetics e.g. granisetron. One study suggests that granisetron prevents early chemotherapy induced emesis in 90% cases while ondansetron prevents in 70% patients.[16] Antacid medications prescribed includes digene (magnesium hydroxide, aluminium hydroxide gel, simethicone, and sodium carboxymethylcellulose), gelusil (aluminium hydroxide, magnesium hydroxide and dimethicone). Manjesh et al study results also stated that the most common antiulcer medication pantoprazole and antacid gelusil.[8] The antiulcer drugs are prophylactically suggested to prevent hyperacidity by the disease or the co medications. Paracetamol was the most common analgesics prescribed followed by tramadol. Several studies stated that efficacy of NSAIDs in cancer pain management.[17] The minerals and multivitamins prescribed included calcimax, vitamin D3, vitamin E as part of nutritional supplement and to tackle the lower bone mineral density.[18] Hexidine mouth wash was prescribed to all ALL patients, since oral healthcare is very crucial in a child undergoing cytotoxic immunosuppressive therapy.[18,19] In present study, among the antibiotics prescribed most commonly prescribed was sulfamethoxazole + trimethoprim followed by magnex

forte (cefoperazone + sulbactum). Prophylactic prescription of antibiotic is recommended as supportive care in ALL patients.

For anticancer medication 100% prescriptions were complete with respect to dose, dosage form, frequency, duration, instructions. In the study, incompleteness in supportive care included omissions in dose, duration, dosage form and frequency. Dose was not mentioned in supportive care which included drugs prescribed by brand name. But for anticancer medication 100% prescriptions were complete indicating following good clinical practice guidelines which can prevent medication errors in Oncology. Prescription error involving injectables which may lead to serious consequences and often be fatal because of their immediate and complete absorption and distribution into the blood stream.

A total 582 adverse drug reactions were identified wherein clinical abnormalities as well as laboratory finding abnormalities as compared to baseline were encountered. Average number of ADR were 4 per patient. 71% were clinical adverse drug reactions and 29% were laboratory diagnosed reactions. Most common laboratory diagnosed ADR was Febrile neutropenia. In Vazquez et al study, total 340 ADR were noted in 147 patients at the end of induction phase in ALL, with average of 2 ADR per patients. Most common ADR was Febrile neutropenia (18.8%) followed by allergic reaction (6.3%) and hyperglycaemia (6.3%).[19] Another study which was a multicentre study with 1872 paediatric ALL witnessed 3190 toxic episodes of grade 3 and grade 4 category, with Infection (32.3%), 28.2% hepatotoxicity and 20.4% gastrointestinal toxicity.[7] For causality assessment both WHO -UMC and Naranjo scales were used, 93.81% and 99.14% ADR were possibly related with both scales respectively.[19-21] For possibly related ADR most common suspect drug was methotrexate causing oral mucositis by WHO UMC and Prednisolone for fungal pneumonia by Naranjo scale.

In the present study, severity was assessed Modified Hartwig Siegel scale, and majority of the reactions were mild (61.51%) in severity, 37.97% moderate severity and 0.51% severe ADR.[21] Sharma et al study reported 41% moderate ADR, Chopra et al reported maximum mild ADR.[22,23] As per Vazquez et al rate of ADR severity was 17.1% moderate, 7.4% was mild, 16.6% was severe per 1000 patients at the end of induction.[19] The Common Terminology Criteria for Adverse Events (CTCAE) classification was not used for grading the severity of ADR and this is the study limitation.

Modified Schumock Thornton scale was used to find preventability of ADR, in the current study 100% ADR were not preventable.[24] All the drugs as per their profile can lead to this ADR which are not preventable but can be managed by supportive care.

This study has few limitations. We have not evaluated patient care indicators, facility specific indicators. As the inclusion criteria was completed 35 days induction phase, we could not capture deaths in the study, because maximum mortality is seen in 1st week of induction phase with infection. Common terminology criteria for adverse events for grading cancer severity was not used.

## CONCLUSION

The commonest type of cancer seen in paediatric ALL was B cell acute lymphoblastic leukaemia. The commonest anti-cancer drugs prescribed are vincristine, methotrexate. The commonest supportive care prescribed is Antiemetic therapy (granisetron). The popular drug regimen used in standard risk is prednisolone, methotrexate, vincristine, peg asparaginase; in intermediate risk and high risk prednisolone, methotrexate, vincristine, daunorubicin, peg asparaginase. The frequent adverse drug reaction found was alopecia (clinical), febrile neutropenia (clinico-laboratory). The commonest drug causing adverse drug reactions was vincristine. 100% of adverse drug reactions were not preventable.

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