REAL WORLD EFFICACY AND SAFETY OF GENERIC BRUTON TYROSINE KINASE INHIBITOR (BTKI) USE IN CHRONIC LYMPHOCYTIC LEUKEMIA AND OTHER INDOLENT LYMPHOMAS IN INDIA

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Introduction

BTK inhibitors (BTKi) have transformed management of CLL and indolent lymphomas worldwide. In India, innovator drugs are inaccessible due to cost. Generic Ibrutinib and Acalabrutinib have been available for ~4 years. Their real-world efficacy and safety data in India remain limited.

Aim

To evaluate the real-world efficacy and safety of generic Bruton tyrosine kinase inhibitors (BTKi) in patients with chronic lymphocytic leukemia (CLL) and other indolent lymphomas in India.

Objectives

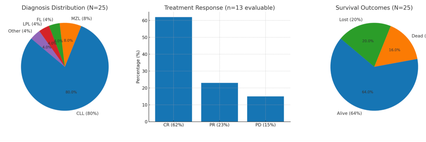
1. To assess the treatment response rates (CR, PR, PD) with generic BTKi.
2. To analyze the safety profile and adverse events associated with generic BTKi.
3. To determine the causes of treatment discontinuation (disease progression, intolerance, financial constraints).
4. To compare outcomes between Ibrutinib and Acalabrutinib in real-world practice.

Methods

- **Design:** Retrospective study
- **Patients:** 25 cases (20 CLL, 5 indolent lymphomas) treated with generic BTKi
- **Drugs:** Ibrutinib (n=15), Acalabrutinib (n=10)
- **Outcomes Measured:**
  - Treatment response (CR, PR, PD)
  - Adverse events
  - Treatment discontinuation and reasons

Results

- **Patient Characteristics**
  - Total patients**:** 25
  - Sex distribution**:** 20 (80%) males, 5 (20%) females
  - Median age**:** 59.3 years (range: 33–95 years)
- **Diagnosis**
  - Chronic Lymphocytic Leukemia (CLL): 20 (80%)
  - Marginal Zone Lymphoma (MZL): 2 (8%)
  - Follicular Lymphoma (FL): 1 (4%)
  - Lymphoplasmacytic Lymphoma (LPL): 1 (4%)
  - Other low-grade B-cell lymphoma: 1 (4%)
- **Treatment**
  - BTKi as frontline therapy: 11 (44%)
  - BTKi as ≥2nd line: 14 (56%)
  - Ibrutinib: 15 (60%)
  - Acalabrutinib: 10 (40%)
- **Comorbidities**: Diabetes mellitus: 4 (16%), Hypertension: 5 (20%), COPD: 1 (4%), Hyperthyroidism: 1 (4%)
- **Response** (n=13 evaluable):
  - Complete response (CR): 8 (61.4%)
  - Partial response (PR): 3 (23.1%)
  - Progressive disease (PD): 2 (15.4%)
- **Frontline BTKi : higher CR than ≥2L (p=0.04)**
- **Adverse events**: Skin Rash 3 (12%), fascial Paresthesias 2 (8%).
- **Treatment discontinuation (n=7;28%):** Progressive disease 3 (12%), Intolerance 2 (8%), Financial reasons 2 (8%).
- **Survival at last follow-up**: Alive 16 (64%), Dead 4 (16%), Lost to follow-up 5 (20%).
- **Toxicity**: No significant difference between ibrutinib and acalabrutinib



Conclusion

Generic BTKi have greatly improved the treatment landscape for CLL by increasing survival rates, where the innovators drugs are not accessible.

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