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Letter to Editor

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Real World Effectiveness and Safety of Super Bioavailable Itraconazole for Glabrous Dermatophytosis in India: A Multi Centre Retrospective Analysis

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Letter to Editor

Dear Editor,

In recent years, India has seen a significant rise in the prescription of itraconazole for the management of dermatophytosis [1]. However, its pharmacokinetic variability has often led to inconsistent clinical outcomes. To address these challenges, a newer formulation-Super-Bioavailable Itraconazole (SB-ITZ) has been commercialized in India [2]. Although SB-ITZ has supportive pharmacokinetic and clinical data, large scale real world evidence remains limited. We therefore undertook a retrospective, record based evaluation of SB ITZ in Indian patients with dermatophytosis.

After obtaining ethics committee approval, we analysed two independent, retrospective cohorts of patients with glabrous dermatophytosis who were prescribed SB ITZ 130 mg daily by treating dermatologists. Sites abstracted data into a predesigned case record form; records with missing key information were excluded. Cohort 1 and Cohort 2 comprised 753 patients across 129 sites and 2,356 patients across 334 sites, respectively. Extracted variables included demographics; prior medications; and clinical parameters like component lesional scores (erythema, scaling, pruritus, margin continuity/elevation), total lesional score and clinical severity/Body Surface Area (BSA) score at baseline, Week 2 and Week 4. Statistical analyses were conducted using R software (version 4.0 or later). Data extracted from patient medical records were pooled and evaluated using standard descriptive statistical techniques. Categorical variables were summarized as frequencies and percentages, with percentages typically calculated using the total number of subjects (N) indicated in the column headers. For variables involving co prescribed treatments, a conditional denominator was applied.

Mean age was 37.0 ± 9.9 years (Study 1) and 38.7 ± 11.5 years (Study 2). Males comprised 65% (489/753) and 63.0% (1,485/2,356), respectively. The principal indication was glabrous tinea (96.4% and 99.6%). Small numbers were treated for other dermatophytoses or superficial mycoses (e.g., tinea cruris/corporis, onychomycosis, candidiasis). Prior medications were infrequent; the most common were antifungals (including terbinafine/itraconazole) in Study 1 and metformin in Study 2. Both cohorts demonstrated rapid, clinically meaningful and statistically significant improvements across all parameters (all $p < 0.001$). Effectiveness scores are depicted in Table 1.

Change in Mean Erythema Lesional Score from Baseline to Week 4				
Visit	Study 1		Study2	
	Mean ± S.D.	p-value	Mean ± S.D.	p-value

Baseline	2.23±0.76	<0.001	2.35±0.65	<0.001
Week 2	1.44±0.64		1.38±0.67	
Week 4	0.31±0.61		0.41±0.68	
Change in Mean Scaling Lesional Score from Baseline to Week 4				
Visit	**Study 1**		**Study2**	
	Mean ± S.D.	**p-value**	**Mean ± S.D.**	**p-value**
Baseline	2.2±0.77	<0.001	2.28±0.65	<0.001
Week 2	1.36±0.67		1.33±0.67	
Week 4	0.29±0.58		0.37±0.66	
Change in Mean Pruritus Lesional Score from Baseline to Week 4				
Visit	**Study 1**		**Study2**	
	Mean ± S.D.	**p-value**	**Mean ± S.D.**	**p-value**
Baseline	2.23±0.74	<0.001	2.33±0.66	<0.001
Week 2	1.4±0.65		1.33±0.68	
Week 4	0.34±0.61		0.38±0.66	
Change in Mean Margin Continuity and Elevation Lesional Score from Baseline to Week 4				
Visit	**Study 1**		**Study2**	
	Mean ± S.D.	**p-value**	**Mean ± S.D.**	**p-value**
Baseline	1.99±0.88	<0.001	2.18±0.74	<0.001
Week 2	1.32±0.64		1.3±0.66	
Week 4	0.32±0.6		0.43±0.66	
Change in Mean Total Lesional Score from Baseline to Week 4				
Visit	**Study 1**		**Study2**	
	Mean ± S.D.	**p-value**	**Mean ± S.D.**	**p-value**
Baseline	8.62±2.78	<0.001	9.13±2.35	<0.001
Week 2	5.52±2.25		5.34±2.33	
Week 4	1.28±2.15		1.59±2.37	

Table 1: Change in effectiveness scores from baseline to week 4 in both studies.

On analysing adverse events in both studies, no adverse event was reported in study 1, whereas 89 (3.78%) patients experienced adverse event in study 2. Out of these, skin exfoliation was most commonly reported comprising of 26 (1.1%) patients followed by rash in 24 patients (1.02%), increased itching in 23 patients (0.98%).

Across 3,109 patients from 463 Indian centres, SB ITZ 130 mg was associated with robust, statistically significant reductions in all effectiveness scores by Week 4, with an acceptable AE profile. These findings are consistent with other published real world studies on SB-ITZ [3-5]. Expert consensus similarly favours SB ITZ based on higher trough concentrations and improved clinical outcomes [6].

To the best of our knowledge, this study represents the first real world data on SB-ITZ in glabrous dermatophytosis. This study highlights the clinical utility of SB-ITZ as one of the preferred systemic antifungals in the armamentarium of glabrous dermatophytosis. Limitations include the retrospective design; absence of a concurrent comparator; reliance on clinician recorded scores; potential under reporting of AEs; and lack of standardized mycological endpoints, relapse data or longer follow up. Nonetheless, the sample size, multi centre breadth, consistency of effect across components and BSA and concordance with prospective evidence strengthen the inference that SB ITZ is effective and well tolerated in current Indian practice.

Keywords: Super Bioavailable Itraconazole; Glabrous Dermatophytosis; Body Surface Area

Conflict of Interest

Dr Kapil Chandra declared no conflict of interest with respect to the research, authorship and/or publication of this article. Dr Dhiraj Dhoot and Dr Pallavi Mishra are employees of Glenmark Pharmaceuticals Ltd, India.

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Data Availability Statement

Data generated during this study is available from the corresponding author on reasonable request.

Ethical Statement

The work presented in this study was in accordance with the study protocol, the New Drugs and Clinical Trials Rules 2019 issued by the Government of India, the ethical principles that have their origin in the Declaration of Helsinki, International Council for Harmonisation (ICH) Good Clinical Practice (GCP) and all applicable local regulatory requirements. Independent Ethics Committee approval was obtained prior to study initiation and data collection.

Informed Consent Statement

Not Applicable.

Authors' Contributions

KC was the principal investigator of the study. PM and DD are the employees of Glenmark.

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