

## Original Research Article

# A real-world, non-interventional Indian study on clinical assessment of intense moisturizing formulation in dry skin disorders

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**Received:** 03 September 2021

**Accepted:** 18 October 2021

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### ABSTRACT

**Background:** Moisturizers account for the largest and important skin care product categories and are the backbone in the management of dry skin conditions associated with atopic dermatitis (AD), psoriasis and ichthyosis.

**Methods:** A multicentre, retrospective data analysis was done at 145 dermatology clinics across India in patients who were prescribed MaxRich®. Patients with history of xerosis with an identifiable causes like AD, psoriasis and ichthyosis were included in study. Effectiveness data in terms of improvement in dry skin area and severity index (DASI) score compared to baseline and physician global assessment at the end of treatment for improvement in xerosis were captured.

**Results:** There was significant reduction in mean DASI score as compared to baseline at week 2 and 4 ( $p < 0.01$ ). As compared to baseline, a significant decrease in DASI score was observed by 47.7% and 82.4% at the end of week 2 and 4 respectively. As per physician global assessment, 458 patients (83.4%) noticed very good improvement in xerosis at the end of 4 weeks whereas 82 patients (14.9%) recorded moderate improvement. Similar results were also obtained for patient global assessment where 478 patients (87%) recorded very good improvement; 67 patients (12.2%) and 6 patients (1.1%) recorded moderate and mild improvement respectively. There were no adverse events reported with MaxRich®.

**Conclusions:** MaxRich®, an intense moisturizer was effective in improvement of DASI score associated with AD, psoriasis and ichthyosis and can be considered as an adjunct therapy in the management of these skin disorders for better results.

**Keywords:** Xerosis, MaxRich, AD, Psoriasis, Ichthyosis, DASI score

### INTRODUCTION

Dry skin or xerosis is a condition of rough, dry, cracked and pruritic skin and affects people of different skin types involving different areas of the body.<sup>1,2</sup> In recent years, rise in incidence of dryness related dermatoses has been noted due to multiple factors like, abandonment of traditional oil massages due to globalization and increased urbanization, pollution and increased life span.<sup>3</sup> Hence to improve xerosis, fruitful repair and restoration of the skin barrier is utmost important<sup>2</sup> and moisturizers are the backbone for repair and restoration. In recent

years, moisturizers account for the largest and important skin care product categories and are found to be beneficial in the management of dry skin associated with AD, psoriasis and ichthyosis.<sup>3,4</sup>

The major function of moisturizers is to maintain the hydration within the stratum corneum and to overcome the skin dryness associated with certain diseases, they may be considered as therapeutic products.<sup>5</sup> There is abundance of moisturizers currently available in the market with different constituents and different claims. But despite their extensive use and applications, the

literature on moisturizers still lacks strong scientific evidence.<sup>3,6</sup>

MaxRich®, an intense moisturizing formula comprising of xylitol, xylitylglucoside and anhydroxylitol has been there in Indian market since last 3-4 years and demonstrated fast and long-lasting moisturizing effect.<sup>7</sup> Our study aimed to analyze the real-world evidence of the effectiveness and safety of MaxRich® moisturizer in the overall management of Indian patients with xerosis associated with skin disorders.

**METHODS**

A multicentre, retrospective data analysis was done at 145 dermatology clinics across India during November 2019 to March 2020 after obtaining ethics committee approval. The data charts were identified by generating a list of all patients ever prescribed MaxRich® at all clinics and maintaining complete assessment records such as safety and efficacy with DASI score, using the electronic medical record database. Eligible patients within age group of 18-60 years and with a clinical history of xerosis with an identifiable causes like AD, psoriasis and ichthyosis were included in study.<sup>8</sup> Effectiveness data in terms of improvement in DASI score compared to baseline and physician global assessment at the end of treatment for improvement in xerosis were captured. Additionally, patient global assessment data was also captured as an exploratory endpoint. Safety data (reported AEs) associated with MaxRich® were also recorded from available data. Paired t test was used to compare proportions with significance of p=0.05.

**RESULTS**

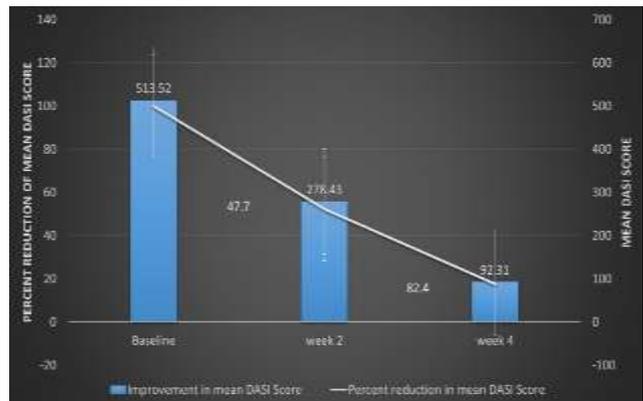
After complete analysis, a total of 549 patients met inclusion criteria and their baseline demographics are summarized in Table 1. The details concerning the primary disease with concomitant medication use by the patients are summarized in Table 1.

There was significant reduction in mean DASI score as compared to baseline at week 2 and 4 (p<0.01) as shown in Figure 1. A significant reduction in DASI scores was observed at the 2<sup>nd</sup> and 4<sup>th</sup> week compared with baseline, with a reduction of 47.7%, 82.4% respectively (Figure 1).

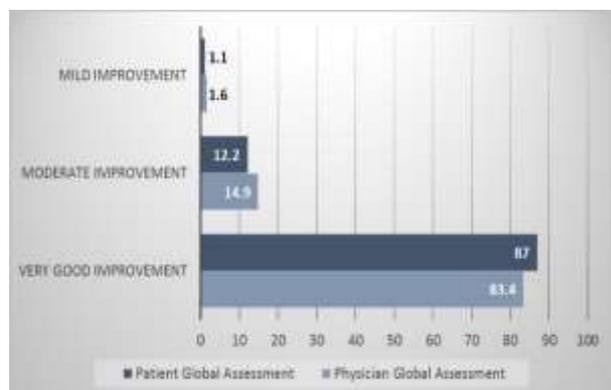
As per physician global assessment, 458 patients (83.4%) noticed very good improvement in xerosis at the end of 4 weeks whereas 82 patients (14.9%) recorded moderate improvement. Rest nine patients (1.6%) showed mild improvement. Similar results were also obtained for patient global assessment where 478 patients (87%) recorded very good improvement; 67 patients (12.2%) and 6 patients (1.1%) recorded moderate and mild improvement respectively (Figure 2). There were no adverse events reported with MaxRich®. It was very well tolerated.

**Table 1: Baseline demographics.**

Parameters	N=549
<b>Average age; years (mean±SD)</b>	34.02±15.50
<b>Sex (N, %)</b>	
Male	331 (60.29)
Female	218 (39.70)
<b>Primary disease (N, %)</b>	
AD	196 (35.70)
Ichthyosis	131 (23.86)
Psoriasis	222 (40.44)
<b>Average disease duration (years±SD)</b>	
AD	0.69±0.24
Ichthyosis	0.70±0.24
Psoriasis	0.72±0.24
<b>Concomitant medications (N, %)</b>	
Antihistamines	350 (63.75)
Oral retinoid	10 (1.82)
Multivitamins	70 (12.75)
Oral and topical antibiotics	32 (5.83)
Immunomodulator	103 (18.76)
Oral steroids	25 (4.55)
Topical steroids	300 (54.64)
Topical immune-modulator	46 (8.38)
Keratolytic	25 (4.55)
<b>Mean DASI score (SD)</b>	513.52±314.59



**Figure 1: Improvement and percent reduction in mean DASI score during study duration.**



**Figure 2: Improvement by physician and patient global assessment at the end of 4 weeks.**

## DISCUSSION

In recent years, moisturizers account for the largest and important skin care product categories and are found to be beneficial in the management of dry skin associated with AD, psoriasis and ichthyosis.<sup>3,4</sup> Multiple guidelines recommend to apply moisturizer generously and frequently in order to maintain the hydration within the stratum corneum, thereby keeping the corneocytes “fluffed up” and closing the cracks leading to restoration of natural barrier function of the skin.<sup>9</sup> In our study, we evaluated real world effectiveness of MaxRich®; an intense moisturizer in the management of dry skin disorders like AD, psoriasis and ichthyosis.

We evaluated improvement in xerosis with the help of DASI. It is a well-known utility tool to diagnose severity of dryness in OPD setup and was already evaluated in some studies.<sup>2,8</sup> In our study, DASI improved by 47.7% in just 2 weeks and by 82.4% in 4 weeks suggesting effectiveness of MaxRich®. Additionally, improvement was recorded on physician and patient global assessment as well. As per physician global assessment, improvement was seen in 98.3% of patients and 99.2% patients recorded the same on patient global assessment. Apart from efficacy, safety was also recorded where none of the patient complained of any adverse effect related to MaxRich®. As per our knowledge, this is the first kind of study regarding clinical assessment of MaxRich®. In an *in vivo* study conducted on MaxRich®, it was found that MaxRich® was associated with a significant increase in skin hydration from baseline after 4 hours and was also able to maintain the same up to 24 hours.<sup>7</sup> Additionally, significant decrease in trans-epidermal water loss was also noted throughout 24 hours. From the study, authors highlighted an intense and long-lasting moisturizing effects with MaxRich®.

MaxRich® is an intense moisturizer with a composition of xylitol, xylitylglucoside, and anhydroxylitol. Xylitol is commonly used as humectant and it was found to amplify collagen formation and suppress sodium lauryl sulfate-induced TEWL in few *in vitro* and *in vivo* studies.<sup>7</sup> Additionally, apart from exerting anti-irritant actions, it also increases filaggrin expression and skin hydration. Similar results of skin hydration and anti-irritant action of xylitol were also collaborated by Szél et al in their experiment.<sup>10</sup> Silva et al in their study, compared the moisturizer containing xylitol, xylitylglucoside, and anhydroxylitol with herbal extract and NMF based gel and concluded that xylitol containing moisturizer produced most intense hydration of skin surface.<sup>11</sup>

Filaggrin plays very important role in epithelial regeneration and barrier repair and xylitol was found to be associated with a noticeable upregulation of filaggrin in a study by Szabó-Papp et al.<sup>12</sup> Proteins, ceramides and enzymes like keratin, loricin are essential for smooth functioning of skin barrier and xylitylglucoside stimulate the synthesis of proteins, enzymes, and ceramides as

reported in a review by Zappelli et al and Korponyai et al also reported similar results with xylitol leading to an upraised expression of filaggrin, a source of NMF.<sup>7,13,14</sup>

Considering all the benefits offered by MaxRich®, we suggest further consideration of its use as an adjuvant therapy in dry skin disorders. In spite of being observational and retrospective in nature with no comparator arm, the real-life clinical practice picture across India was duly captured.

There are certain limitations of the study, i.e., non-evaluation of the repercussion of concomitant medications; no follow-up period and various confounding factors affecting the efficacy response. Future controlled comparative trials are recommended to ameliorate the above-mentioned limitations and reinforce the usefulness of MaxRich® in dry skin disorders.

## CONCLUSION

MaxRich®, an intense moisturizer was effective in improvement of DASI score in dry skin disorders associated with AD, psoriasis and ichthyosis and can be considered as an adjunct therapy in the management of these skin disorders for better results.

## ACKNOWLEDGEMENTS

Authors like to thanks all the dermatologists who participated in this retrospective study and provided their data for analysis. Authors would also like to acknowledge Dr. Gaurav Deshmukh (Ex-employee of Glenmark pharmaceuticals for collating data and analysis.

*Funding: No funding sources*

*Conflict of interest: None declared*

*Ethical approval: The study was approved by the institutional ethics committee*

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**Cite this article as:** Dhoot DS, Mahadkar N, Barkate H. A real-world, non-interventional Indian study on clinical assessment of intense moisturizing formulation in dry skin disorders. *Int J Res Dermatol* 2021;7:848-51.