Improving Patient's Quality of Life Using a Ceramide-Containing Moisturiser as Monotherapy in Mild to Moderate Atopic Dermatitis

Poster ###

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1. INTRODUCTION AND OBJECTIVES

- Atopic dermatitis (AD) is associated with altered levels and composition of ceramides which are instrumental in maintaining skin barrier function (SBF), hence their resultant skin barrier dysfunction.[1]
- Ceramide-containing moisturiser (CCM) was formulated as a multivesicular emulsion (MVE), which is a novel technology consisting of vesicles of oil-in-water emulsion held within another vesicle, ensuring gradual release of active ingredients over time, as vesicles open sequentially (Fig. 1).[2]
- In this study, we evaluated:
  - Improvement in patient's quality of life
  - Reduction in severity of AD
  - Restoration of SBF
- In 120 Indian patients with mild to moderate AD, when they used a CCM (formulated as an MVE) as monotherapy for 4 weeks.

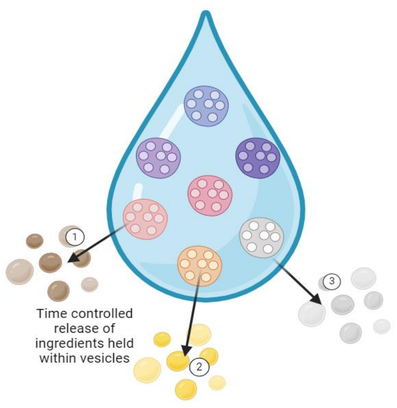

Fig. 1: Multivesicular emulsion (MVE) ensures gradual release of active ingredients over time, as vesicles open sequentially.

2. METHODOLOGY

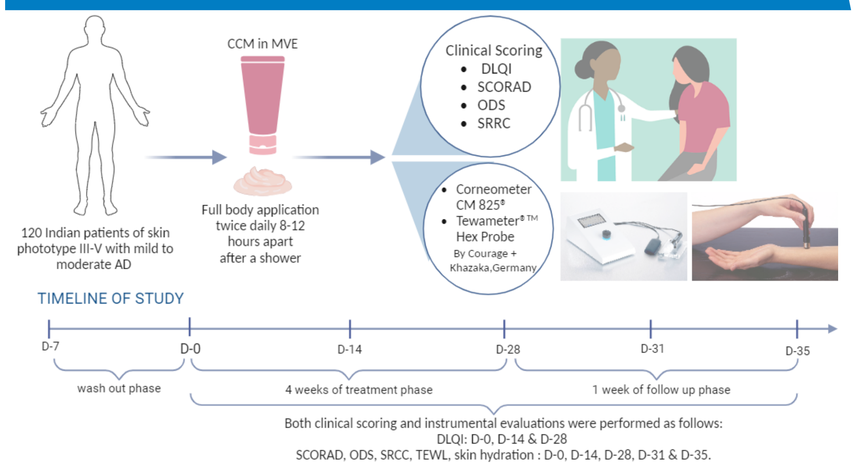

Fig. 2: Study flow

- One hundred twenty adults with 'SCORAD categorized' mild to moderate AD applied CCM twice daily over entire body as monotherapy for 28 days (4 weeks of treatment phase)[3], followed by a 7-day treatment-free follow up phase, during which no moisturizer was applied (Fig. 2).
- Dermatology Life Quality Index (DLQI)[4,5] was assessed at D-0 (baseline), D-14 & D-28 (treatment phase), while SCORAD[6], overall dryness score (ODS), scaling, roughness, redness & cracks (SRRC) grading, numerical rating scale (NRS) for average itch, transepidermal water loss (TEWL), skin hydration & adverse effects were assessed at D-0 (baseline), D-14 & D-28 (treatment phase), & also on D-31 & D-35 (treatment-free phase), Additionally ODS, SRRC, TEWL & skin hydration were assessed 15 minutes after 1st application of CCM.
- A questionnaire to assess patient satisfaction with CCM on 19 parameters was administered to patients at end of treatment.

3. RESULTS AND DISCUSSION

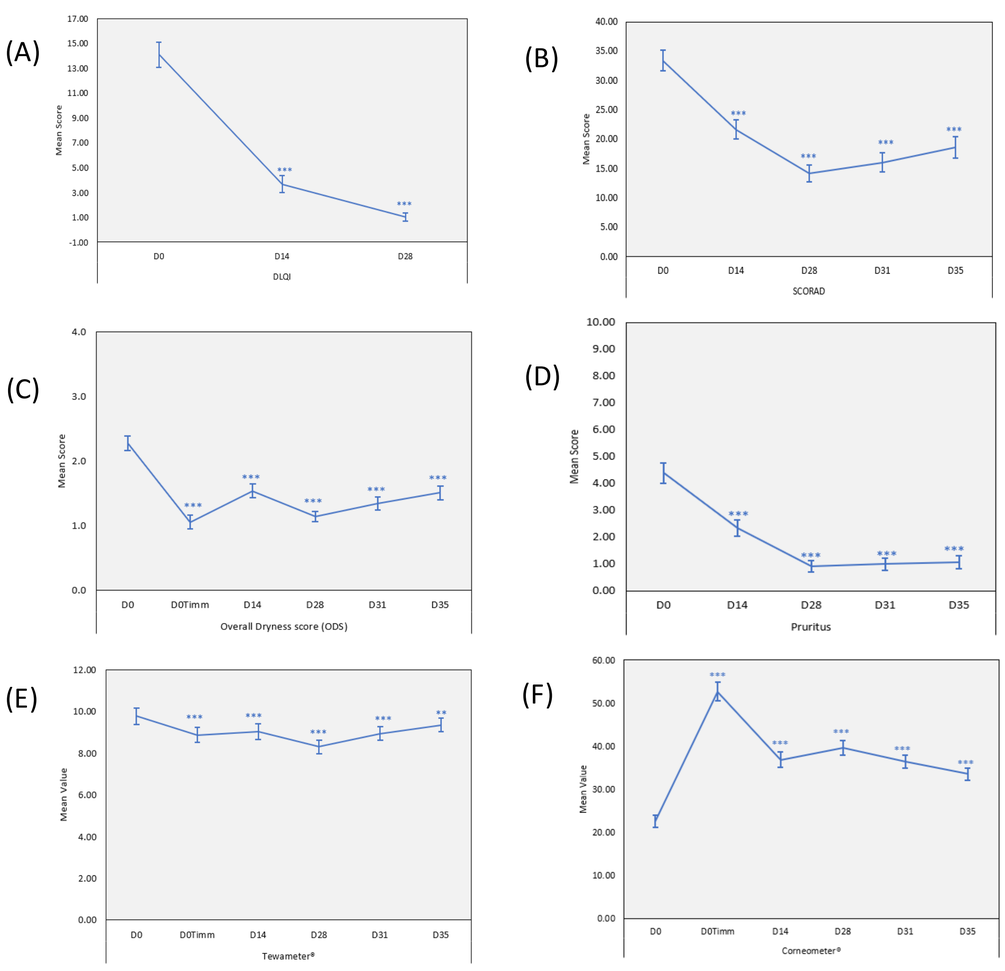

Fig. 3: (A) DLQI, (B) SCORAD, (C)ODS, (D) Pruritus, (E)Tewameter and (F) corneometer measurements between D0 & D35 ** *p*-value ≤ 0.01 & *** *p*-value ≤ 0.001.

- Of 120 enrolled participants, 117 completed the study.
- A statistically significant improvement in mean of % change in scores from D-0 was noted:
  - On D-14 & D-28, in DLQI: **-**72.6 & **-**91.2% respectively using Wilcoxon test (Fig. 3A).
  - On D-14, D-28, D-31 & D-35 in SCORAD: **-**34.5, **-**56.5, **-**51.1 & **-**43.5% respectively (*p*< 0.001, using paired *t*-test; Fig. 3B).
  - On D-14, D-28, D-31 & D-35 in ODS: **-**31.8, **-**48.9, **-**40.2 & **-**33.1% respectively (*p*< 0.001, using Wilcoxon test; Fig. 3C).
  - On D-14, D-28, D-31 & D-35 in SRRC: **-**37.4, **-**61.7, **-**51.0 & **-**42.5% respectively (*p*< 0.001, using Wilcoxon test).
  - On D-14, D-28, D-31 & D-35 in NRS for average itch: **-**33.9, **-**61.4, **-**56.9 & **-**51.7% respectively (*p*< 0.001, using Wilcoxon test; Fig. 3D).
  - On D-14, D-28, D-31 & D-35 in TEWL: **-**7.5, **-**14.6, **-**8.2 & **-**4.2% respectively (*p* < 0.001 for all timepoints except for D-35, p=0.002, using paired *t*-test; Fig. 3E).
  - On D-14, D-28, D-31 & D-35 in skin hydration: **+**61.8, **+**73.7, **+**59.6 & **+**47.6% respectively (*p*< 0.001, using Wilcoxon & paired *t*-test; Fig. 3F).

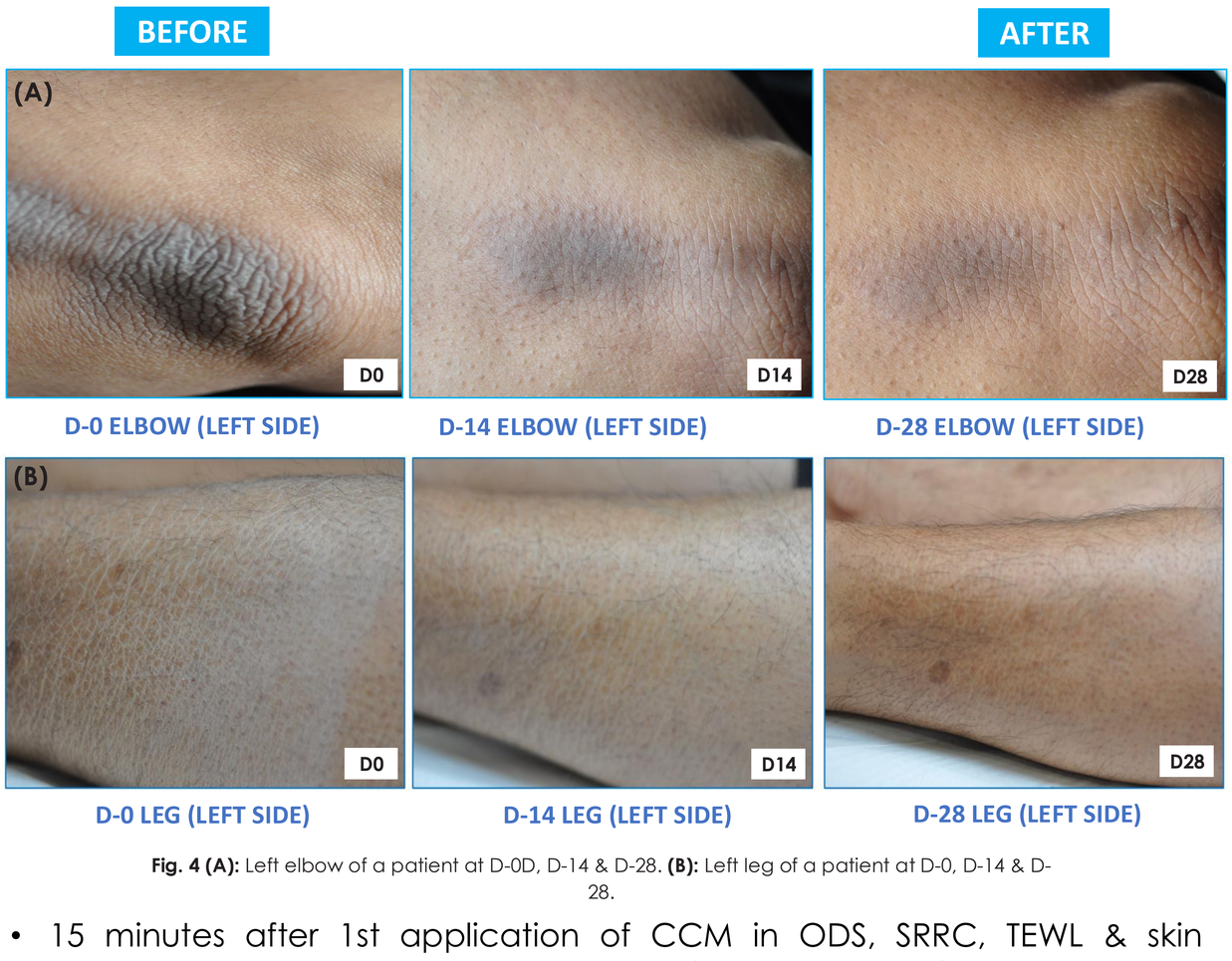

Fig. 4 (A): Left elbow of a patient at D-0D, D-14 & D-28. **(B):** Left leg of a patient at D-0, D-14 & D-28.

- 15 minutes after 1st application of CCM in ODS, SRRC, TEWL & skin hydration: **-**54.0, **-**54.6, **-**9.1 & **+**132.9% respectively (*p* <0.001, using Wilcoxon & paired *t*-test).
- On D-28, in 84 (70.0%) patients there was >50% reduction in SCORAD, while in 104 (86.7%) patients there was at least 1 grade improvement in ODS (Figs 4A & 4B).
- No side effects were noted.
- There was 96.6% cosmetic acceptability of CCM on all parameters evaluated.
- **Limitations of study**: Lack of a comparator arm using a ceramide containing moisturiser, not formulated using MVE technology.

4. CONCLUSION

Our study demonstrates immediate & prolonged efficacy of a ceramide-containing moisturizer formulated using multivesicular emulsion technology when used as monotherapy in mild to moderate AD as demonstrated by improvement in skin barrier function & severity of AD, resulting in significant improvement in patient's quality of life. The study also indicates the improvement in clinical parameters persist for at least 7 days after treatment is stopped, indicating a significant residual effect attributable to restoration of skin barrier function.

5. REFERENCES

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Conflicts of Interest: AJ received fees for her role as dermatologist investigator in clinical trial involving the investigational product, which was developed by L'Oréal India Pvt Ltd. NK received consultancy fees for providing advice & input in design of this study & preparation of poster. CK, RR, HP, NB, AB & AK are employees of L'Oréal India Pvt Ltd or Cerave L'Oréal New York, involved in product development & marketing.