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Original Research Article

Real-world prescribing patterns of topical agents and treatment outcomes in melasma: a retrospective analysis

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ABSTRACT

Background: The present study aims to address the existing evidence gap by assessing prescription patterns for melasma management. Additionally, therapeutic effectiveness is measured through the melasma area and severity index (MASI) score over a structured 3 months observational period.
Methods: The present study is a retrospective, observational, multicentre study that includes data from dermatology OPD across various centres in India. The primary outcome was the assessment of frequency and type of topical agent prescribed, determining prescribing patterns of topical agents. Secondary outcomes included evaluation of effectiveness and safety of topical agents with changes in MASI score from baseline to 3 months post-treatment. Data from all centres were collected as per the protocol and proforma and compiled to summarize prescribing pattern of topical agents and associated demographic data.
Results: The prescribing patterns showed that there was greater use of depigmenting agents. Most frequently used depigmenting agents were kojic acid (KA) (70.72%) and hydroquinone (HQ) (70%). Mean reduction in MASI score of 39.5% was identified from baseline to 3 months post-treatment. Adverse event frequency was relatively minimal. Most patients tolerated the treatment well. Few patients experienced adverse events such as skin irritation (0.46%), erythema (0.24%), peeling (0.18%), and hyperpigmentation (0.16%).
Conclusions: This retrospective study provides an understanding of the role of KA and HQ as common prescribing topical agents for the management of melasma, exhibiting a safe and tolerable profile in large sample size. Significant improvement in MASI scores in 3 months suggests therapeutic advantage in routine clinical practice for melasma treatment.

Keywords: Melasma**,** Kojic acid, Hydroquinone, Melasma area and severity index

INTRODUCTION

Melasma is a skin condition caused by excessive melanin production in areas exposed to UV light. The most common affected areas include the face and, less commonly, the forearms and neck.[1] Melasma presents clinically with varied shades of light and dark brown, symmetrically as macules and irregular patches.[2] This genetic pigmentary condition affects Asian women, largely during pregnancy and the reproductive phase.[1] In India, melasma affects about 20-30% of women between the ages of 40 and 65, and it can affect up to 70% of pregnant women.[3] The main etiologic factors contributing to melasma include sun exposure, hormonal changes, and skin barrier dysfunction (acne).[4] Several topical agents are available for the management of melasma.[5] The gold standard treatment is HQ owing to its superior efficacy.[6] Other topical treatment options include KA, ascorbic acid, tranexamic acid, retinoids, niacinamide, steroids, azelaic acid, and salicylic acid. Triple combination therapy, including HQ, a steroid, and a retinoid, has shown potential efficacy as a first-line treatment option

for melasma management.[7] Recent studies have investigated the role of newer depigmentation agents in the management of melasma to overcome the side effects of topical agents.[8]

As melasma shows female gender dominance, women tend to get conscious about its clinical presentation owing to cosmetic issues.[7] Correct identification of the condition and timely diagnosis are often complicated by its varied clinical patterns, resulting in delayed treatment and follow-up, as recommended by dermatologists. This results in prolonged treatment processes and management difficulties.[9] Due to the melasma presentation on the central face, cheeks, temple, and forehead, the condition can severely impact self-esteem, emotional well-being, and quality of life.[10] Considering a wide spectrum of available management modalities, the pattern of use of different topical agents, and inconsistent treatment outcomes, there is a lack of research to assess the suitability of medical and cosmetic interventions.[11] To assess the severity of melasma, a reliable tool is used, referred to as the MASI, which successfully assesses the progression of this skin condition.[9] MASI, originally introduced by Kimbrough-Green et al was developed as a standardized tool to quantitatively assess the severity of melasma and monitor therapeutic response over time.[12] The MASI scoring system evaluates three key parameters: the extent of involved area (A), the uniformity or homogeneity of pigmentation (H), and the pigmentation intensity.[12] Evidence shows that newer agents, such as cysteamine cream, showed a reduction in MASI score and good tolerability following their application.[13] Additional tools that measure the disease-specific health-related quality of life (HRQOL), such as quality of life in melasma (HRQ-melasma), determine the areas of a patient's life most commonly impacted by dermatosis, as well as the general functionality, to assess the overall quality of life.[14]

Evidence indicates that melasma management recurs and is resistant to traditional therapy, necessitating the importance of topical therapies. Hence, it is crucial to understand the underlying pathogenesis contributing to melasma and prevent the occurrence of this skin condition.[9] The intricate pathogenesis of melasma, combined with its considerable variability in therapeutic responsiveness, underscores the necessity of systematically examining real-world prescribing practices. This will help to objectively evaluate clinical treatment outcomes.[9]

The present study aims to address the existing evidence gap by assessing the prescription patterns for melasma management. Additionally, the therapeutic effectiveness is measured through the MASI score over a structured three-month observational period. The retrospective analysis of clinical records obtained from dermatology outpatient settings will offer meaningful, practice-relevant insights into the most commonly used treatment modalities. Furthermore, clinical outcome assessment was investigated in terms of MASI score changes.

METHODS

Study design

The present study is a retrospective, observational, multicenter, study that includes data from dermatology OPD across various centres in India. The primary aim of the study is to assess the common prescribing patterns of topical agents used in the treatment of melasma. The secondary objective is to evaluate the changes in MASI scores from baseline to 3 months post-treatment as per retrospective data.

Study population

Data was collected retrospectively from different centres across India, including clinics, hospitals, and healthcare institutions. Dermatologists collected the data as study case report form. Patient selection was entirely based on the treating physician's discretion. No additional data collection was performed beyond what was already available in the OPD records.

Eligible participants were recruited. Patients aged 18-60 years who were diagnosed with melasma (as per OPD records), underwent treatment with one or more topical agents for at least 3 months, and had MASI score post-treatment at baseline and 3 months, with complete medical records for follow-up, were included.

Participants with incomplete or missing medical records, pregnant or lactating women, those who underwent treatment with systemic therapy, and those with comorbidities affecting pigmentation (e.g., Addison's disease) were excluded from the study.

Outcome measure

The primary outcome was the assessment of the frequency and type of topical agent prescribed, determining the prescribing patterns of topical agents. Secondary outcomes included the evaluation of the effectiveness and safety of the topical agents with changes in MASI score from baseline to 3 months post-treatment. This includes the evaluation of the effectiveness of the topical agent in terms of changes in the MASI scores from baseline to 3 months post-treatment. The safety of the treatment is measured in terms of the incidence of adverse events determined during the course of treatment, including erythema, irritation, peeling, or contact dermatitis

Data collection

Data was collected via the protocol and the proforma from all the involved centres. The data records included patient demographics (age, gender, duration of melasma,

risk factors, family history of melasma, and Fitzpatrick skin type). Baseline topical agent prescription patterns and MASI scores were recorded at initial presentation. Post-treatment data at 3 months included MASI score reassessment for effectiveness evaluation and documentation of treatment-emergent adverse events.

Data compilation and analysis

Data from all the centres were collected as per the protocol and proforma and compiled to summarize the prescribing pattern of topical agents and associated demographic data.

Statistical analysis

Data collection and analysis were performed using SPSS software. Continuous variables were reported in mean±SD format, while categorical variables were presented in frequencies and percentages. Demographic and clinical variables, along with the prescription trends of topical drugs, were described using descriptive statistics. Because patients can be prescribed multiple topical drugs simultaneously, drug utilization rates were computed separately for each category of drugs used. The main variable of interest was the reduction in MASI score from baseline to 3 months later.

To test the effect of treatment, a paired t-test was utilized by comparing pre- and post-treatment MASI scores for individual patients. The mean difference in MASI scores was derived by subtracting baseline scores from follow-up scores. Statistical significance was tested using a two-tailed $p<0.05$. Significance level was set at 95%. All statistical analyses were based on the assumption of normally distributed continuous variables because of the sample size.

Ethical considerations

Ethical approval was obtained from the relevant ethics committee (EC) before the commencement of data extraction. Due to the retrospective nature of the study and the use of anonymized patient data, a waiver of informed consent was sought.

RESULTS

There was a total of 9610 patients with melasma who comprised the data for statistical analysis. The average age of the subjects was 32.62±8.76 years.

Females dominated with 6345 (66.02%) while males numbered 3265 (33.98%). There was a preponderance of type III Fitzpatrick skin with 31.80%, followed by type IV (25.14%), type II (19.21%). The least common were types V and VI (Table 1).

On average, the length of the disease process was 3.50±2.61 years. The areas commonly affected were cheeks (61.69%) and forehead (55.54%), followed by the upper lip (25.05%) and chin (23.68%). The neck was the least affected area with 9.80%. The results are presented in Table 2.

The prescribing patterns showed that there was higher utilization of depigmenting agents. Most frequently used depigmenting agents were KA (70.72%) and HQ (70.00%). From among HQ products, 2% concentration (80.75%) was more commonly used.

The most frequently used concentration of KA was 4% (54.81%) followed by 2% (33.03%). In azelaic acid products, 20% concentration (25.80%) was uniformly used. Glycolic acid (23.82%), tranexamic acid (15.62%) and ascorbic acid (12.16%) were also used.

Retinoids (10.88%), mainly tretinoin and triple combination (10.63%) were also used in some patients. Corticosteroids were used in 8.54% of patients; however, the low-potency corticosteroids were more commonly used.

Combination therapy was more commonly prescribed than monotherapy, accounting for 69.2% of treatment approaches, while monotherapy constituted 30.8% of prescriptions.

Amongst all the different medications, once daily (OD) frequency of administration was most frequently observed while twice daily (BD) and thrice daily (TID) were observed rarely. Duration of treatment with all the drugs ranged between-2.56 months.

All details regarding medication use, concentrations, administration frequencies, duration of therapy and combinations are listed in Figure 1 and 2 below.

Adjuvant therapies were rarely used amongst patients. Sunscreen was used in 22.92% while moisturizer was prescribed in only 1.19% patients. These observations are shown in Table 3 below.

Statistically significant change in the severity of melasma was noted after treatment. A mean reduction of 2.5328 and a mean MASI score decline of 39.5% was recorded from 6.4087±7.3404 before treatment to 3.8759±4.9723 at 3 months post-treatment. This data is illustrated in Figure 3 below.

Adverse event frequency was relatively minimal. Ninety-nine percent (99.15%) of participants experienced zero side effects. Skin irritation was the most frequently occurring event (0.46%), followed by erythema (0.24%), peeling (0.18%), as well as the hyperpigmentation (0.16%).

Contact dermatitis and hypopigmentation were observed infrequently. This data is shown in Table 4 below.

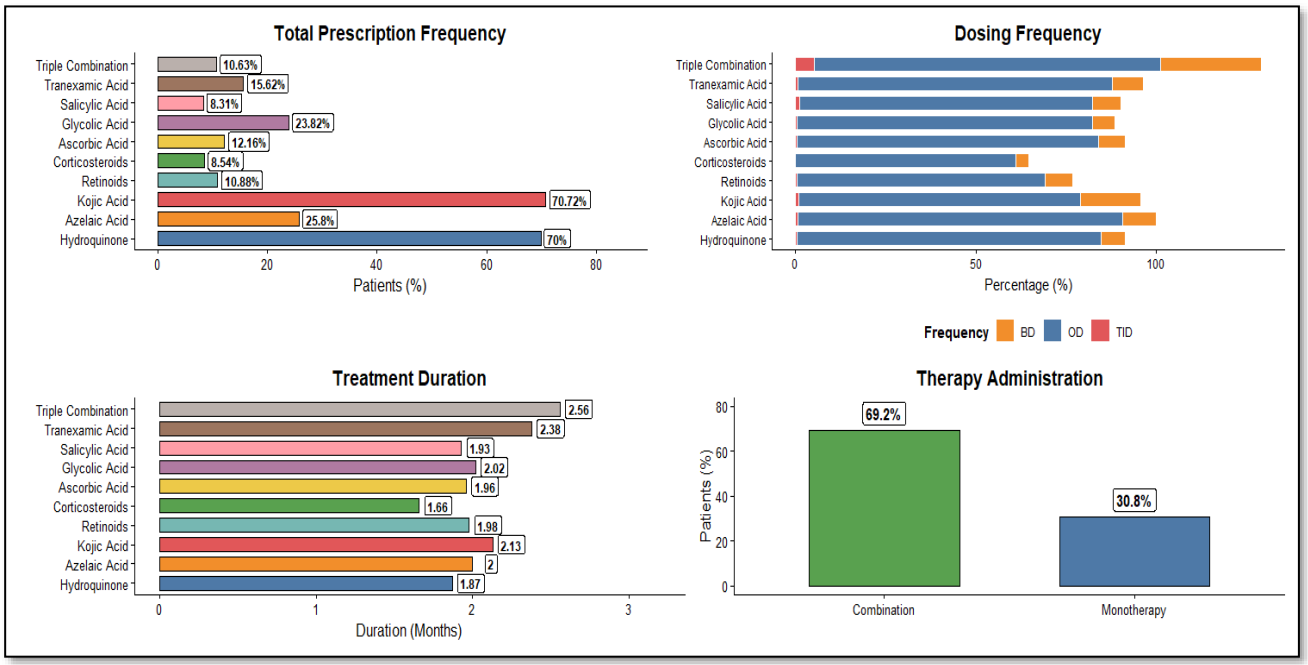

Figure 1: Prescribing patterns of topical agents in melasma, (n=9610).

*Multi-panel graphical representation of prescribing trends and treatment characteristics among patients receiving topical therapy for melasma. (A) Total prescription frequency of individual topical agents expressed as percentage utilization. (B) Distribution of dosing frequency patterns categorized as once daily (OD), twice daily (BD), and thrice daily (TID). (C) Mean duration of therapy (months) for each topical agent. (D) Overall therapy administration pattern showing the proportion of patients receiving monotherapy versus combination therapy. Values are presented as percentages or mean duration in months, as appropriate.

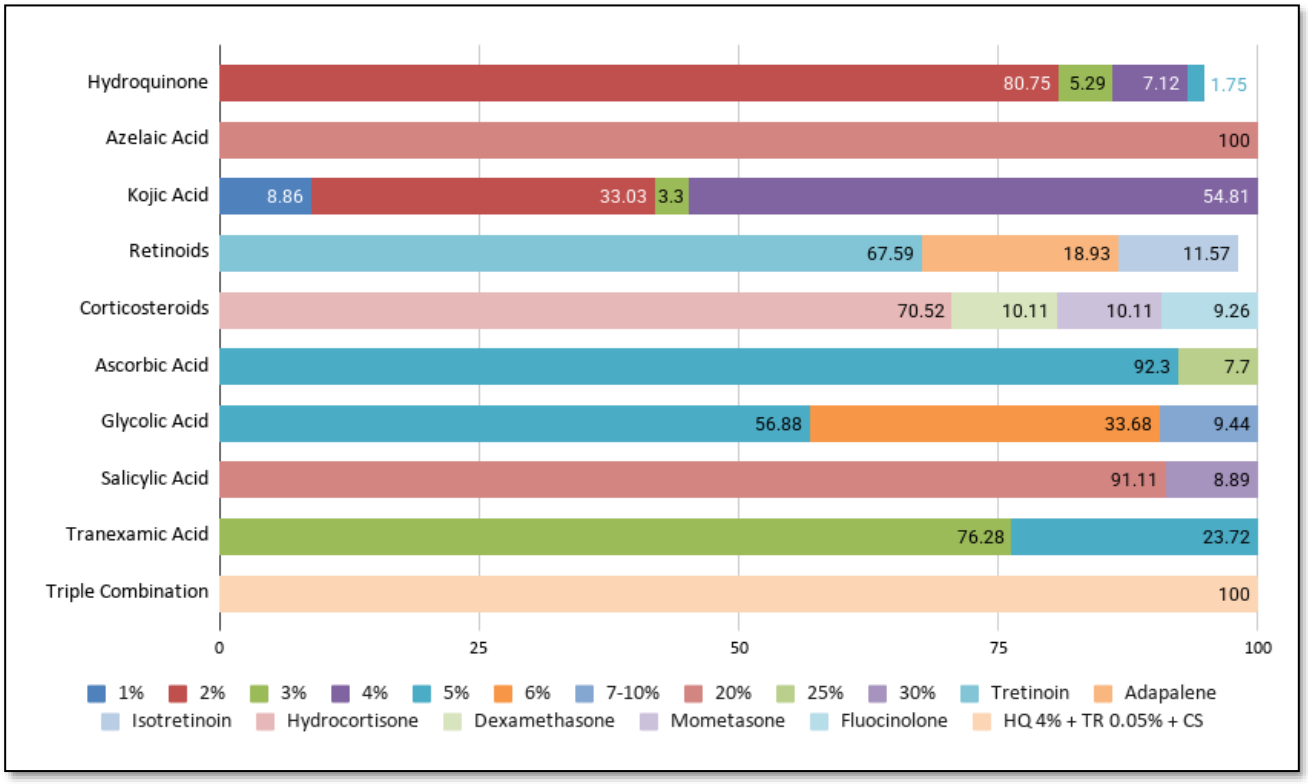

Figure 2: Concentration distribution of commonly prescribed topical agents in melasma.

*Stacked bar chart illustrating the concentration-wise distribution of commonly prescribed topical agents used in melasma management. Each horizontal bar represents the proportional distribution of different strengths or formulations within a therapeutic class. Labels within the bars denote the concentration/formulation and corresponding percentage contribution.

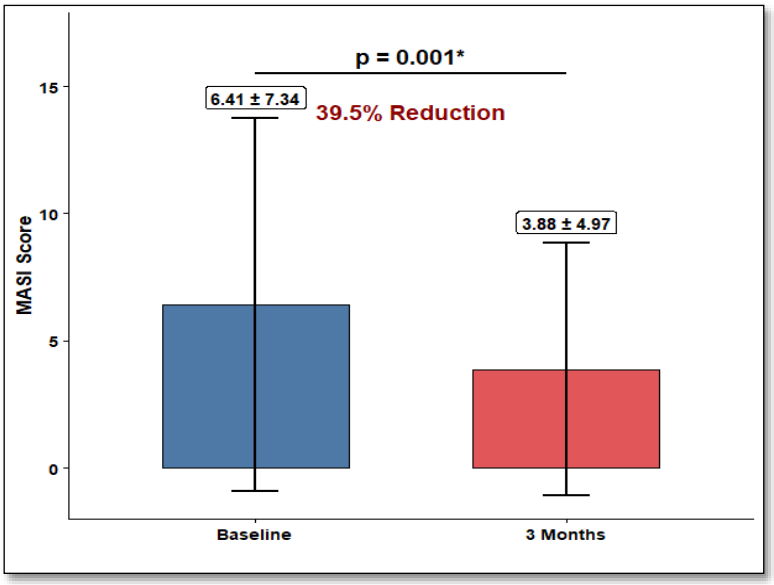

Figure 3: Treatment outcomes based on MASI score, (n=9610).

*Bar graph depicting the mean MASI scores at baseline and after 3 months of treatment, presented with standard deviation (SD) error bars. p value significant at 95% CI using paired t test.

Table 1: Demographic characteristics of study participants, (n=9610).

Variables	Value
Age (in years), mean±SD	32.62±8.76
Gender	
Male	3265 (33.98%)
Female	6345 (66.02%)
Fitzpatrick skin type	
I	1549 (16.12%)
II	1846 (19.21%)
III	3056 (31.80%)
IV	2416 (25.14%)
V	640 (6.66%)
VI	103 (1.07%)

Table 2: Clinical characteristics of melasma, (n=9610).

Variables	Value
Duration of melasma (months)	104.92±78.16
Duration (years), mean±SD	3.50±2.61
Site of involvement	
Cheeks	5928 (61.69%)
Forehead	5337 (55.54%)
Upper lip	2407 (25.05%)
Chin	2276 (23.68%)
Neck	942 (9.80%)
Others	6 (0.06%)

Table 3: Adjunctive therapy.

Treatments	N (%)
Sunscreen	2203 (22.92)
Moisturizer	114 (1.19)

Table 4: Adverse events.

Events	N (%)
No adverse events	9528 (99.15)
Skin irritation	44 (0.46)
Erythema	23 (0.24)
Peeling	17 (0.18)
Hyperpigmentation	15 (0.16)
Contact dermatitis	4 (0.04)
Hypopigmentation	3 (0.03)
Others	1 (0.01)

DISCUSSION

The present study demonstrates the demographic and clinical variables, along with the prescription trends of topical medications for the management of melasma. Baseline demographics showed that the average age of the subjects was 32.62±8.76 years, with a female preponderance. Similarly, other studies have also demonstrated a female predominance in melasma, with the highest prevalence observed among individuals in the third and fourth decades of life.[15,16] In the present study, most of the participants had type III Fitzpatrick skin and type IV. On average, the duration of disease was 104.92±78.16 months (3.50±2.61 years), and common areas affected were the cheeks and forehead, similar to the areas seen in other studies.[15]

The prescribing patterns showed that the most frequently used depigmenting agents were KA and HQ. In the present study, among formulations containing HQ, the 2% strength emerged as the most commonly prescribed concentration. Similarly, for KA-based preparations, the 4% concentration was used most frequently. These

findings are in contrast to a systematic review that included 174 RCTs, where KA 2% cream was the most commonly prescribed topical agent, and considered a suitable alternative to non-HQ agents.[17] Additionally, the review demonstrated the superior outcome with the combination therapy of KA (1%) and HQ (2%) compared to KA monotherapy (2%). These results highlight the potential role of HQ and KA in improving the clinical presentation of melasma.

Several studies have compared the frequency and prescribing patterns of topical agents, and varied outcomes were reported.[17,18] The majority of the existing literature showed that HQ is the most effective treatment option for managing melasma compared to other topical agents. A systematic review including topical and systemic treatment modalities for melasma management, reported that KA, HQ, azelaic acid, and sunscreens were widely recommended for melasma.[17] This is in alignment with the present study, where topical medications such as KA and HQ were the most frequently prescribed. On the other hand, in another study, Kligman's formula (0.1% tretinoin, 0.1% dexamethasone, 5.0% HQ, and hydrophilic ointment) was the most commonly prescribed topical agent in contrast to the existing study.[15] Contrary to the present study, another randomized controlled trial (RCT) demonstrated superior clinical improvement with triple combination (TC) cream, with favorable outcomes observed in 64% of participants, compared with 39% among those treated with 4% HQ (HQ).[5] Studies have shown that a triple combination cream consisting of 0.01% fluocinolone acetonide, 0.05% tretinoin, and 4% HQ demonstrated greater effectiveness in melasma management compared to 4% HQ alone or other combination therapy.[19,20]

Topical agents remain the gold standard for the management of several types of hyperpigmentation conditions, with HQ as the first choice for treating melasma in various countries. HQ is a topical agent that belongs to the phenolic group, popularized as an effective anti-melanogenic agent.[9] The mechanism of action involves the inhibition of tyrosinase by inhibiting the conversion of 1-3,4-dihydroxyphenylalanine to melanin.[21] HQ causes inhibition of RNA and DNA synthesis, altering the formation of melanosomes. This destroys the melanocytes that suppress the metabolic process of the melanocytes, and slows down the production of melanin.[22] The application of topical agents, especially HQ, can be continued for 12 months, and the depigmentation effect is noticeable after 5-8 weeks of application of topical agents.[23]

Over the years, several drugs have proven effective in treating melasma.[24] Since its discovery in the late 1980s, KA has been used to lighten skin by inhibiting tyrosinase and its antioxidant properties.[25,26] For hyperpigmentation, it is a common over-the-counter ingredient.[26] KAis extracted from certain fungi such as *Penicillium* spp., *Aspergillus oryzae* and *Acetobacter* spp. KA blocks tyrosinase activity by binding to copper, and limiting eumelanogenesis.[22] For the management of melasma, the commonly used concentration of KA varies between 1%-4%, showing improvement in skin pigmentation after 2-4 weeks of daily use, with progressive improvement up to 6 months, similar to the outcomes seen in the present study.[27] The difference in the effectiveness of treatment outcomes with HQ, KA, and TC can possibly be attributed to skin types and the type of melasma.[5] A higher difference in effectiveness among the topical agents was reported in individuals with darker skin types and those with mixed types of melasma.[28]

Amongst all the different medications, once daily (OD) frequency of administration was most frequently observed. The duration of treatment ranged between 7 and 11 weeks, as seen with other studies.[28,29] The safety and effectiveness of topical HQ are dependent on the agent's concentration, chemical stability, and vehicle used. Traditionally, HQ is available as a topical cream at a concentration of 2-5%, with application twice daily at bedtime when starting therapy.[22] In the present study, a mean reduction in MASI score of 39.5% was identified from baseline to 3 months post-treatment. This is in accordance with another study that reported a mean reduction in MASI score of 30-40% and 45-55% with topical HQ (4%) after 8 weeks and 16 weeks, respectively.[30,31]

In the present study, sunscreen was commonly used as an adjuvant therapy. Experts recommend the regular use of broad-spectrum sunscreens protects against both UVA and UVB radiation, with a sun protection factor (SPF) of ≥30. In addition, effective photoprotection should include high coverage against UVA1 and high-energy visible light (HEVL).[9] Given their broad range of photoprotective activity, inorganic filters, especially zinc oxide and titanium dioxide, must be used to achieve such broad-spectrum protection. Moreover, formulations with iron oxide pigments are advised because they provide extra defence against UVA1 and HEVL radiation.[32]

In the present study, the majority of the participants did not experience any side effects after application of topical agents. The most frequent side effects were skin irritation, erythema, peeling, and hyperpigmentation. A study reported that the application of HQ often results in adverse effects, including redness, irritative and allergic contact dermatitis, and telangiectasias.[22] Additionally, higher concentrations of HQ cause exogenous ochronosis. Although topical medications for melasma are regarded as a safe option for melasma treatment, but they should be avoided in pregnant females.[22]

The present study has several strengths. Overall, the large sample size (n=9610) enhances the robustness and generalizability of the findings, highlighting the prescribing trends towards KA and HQ for the management of melasma. A detailed evaluation of prescription patterns, such as the type and concentration

of topical agents, frequency, and duration of application, along with the use of adjunctive therapies, reflects the real-world clinical practices among Indian dermatologists. Additionally, the change in the MASI score provided an objective assessment of the therapeutic effectiveness of topical agents. Evaluation of the adverse events demonstrated a favorable safety profile of various treatment modalities.

Limitations

Certain limitations should be acknowledged. Firstly, a retrospective study design limits the ability to establish causal relationships between prescribed therapies and clinical outcomes. Secondly, a short follow-up of 3 months could possibly limit the understanding of the long-term effectiveness and delayed side effects associated with topical agents. Thirdly, as data was collected through medical records, the findings may have reporting bias due to missing or incomplete data, causing inaccuracy in retrospective data collection. Fourthly, an absence of a comparator group makes it challenging to assess the relative efficacy of different topical therapies and evaluate the clinical outcome of one regimen over another.

CONCLUSION

This retrospective study provides an understanding of the role of KA and HQ as common prescribing topical agents for the management of melasma, exhibiting a safe and tolerable profile in a large sample size. A significant improvement in MASI scores in three months suggests therapeutic advantage in routine clinical practice for melasma treatment. A multidisciplinary approach that includes cosmetic surgeons, dermatologists, and skincare professionals will provide meaningful direction tailored to specific patient needs. Further research is required to identify the best combination of topical drugs and assess which combination therapy could produce a better treatment plan for the melasma group.

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