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Original Article

DRUG THERAPY OF HYPOPIGMENTARY DISORDERS OF THE SKIN: A HOSPITAL-BASED STUDY

GIRISH K.[1], NEEPU GOWDA[2], JYOTHI R.[3], VIJAYAMATHY ARUNNAIR[4*]

[1,2,3]Department of Pharmacology, Kempegowda Institute of Medical Sciences, Bangalore, [4*]Department of Pharmacology, KMCH Institute of Health Sciences and Research, Coimbatore

Email: vijiabhi75@gmail.com

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ABSTRACT

Objective: To determine the pattern of drug use, adverse events (AEs), and quality of life (QOL) in hypopigmentary disorders of the skin.

Methods: A prospective, observational study was conducted on 48 newly diagnosed and untreated participants with hypopigmentary disorders who attended the dermatology outpatient department (OPD) of a tertiary care hospital in Bangalore, India. The pattern of drug therapy and AEs to the therapy were analyzed using descriptive statistics. The dermatology life quality index (DLQI) score for QOL was assessed before and after treatment using analysis of variance (ANOVA). The participants were monitored every 30 d for three months to study the appropriateness and changes in prescription patterns, AEs, and QOL.

Results: Male participants had a mean age of 36.69±15.58, while female participants had a mean age of 40.96±11.88. The different classes of drugs used were calcineurin inhibitors, growth factors, melanizing agents, glucocorticoids (GCs), antifungals, and anti-lepra drugs. QOL improved after treatment. The most common AEs include gastritis (16.6%) and acneiform eruption (10.41%).

Conclusion: This study has helped in determining the different patterns of drugs used in hypopigmentary disorders and their positive impact on QOL. The individualized prescribing pattern could improve the clinical and psychosocial outcome of the disease in the future.

Keywords: Quality of life, Topical therapy, Phototherapy

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INTRODUCTION

Hypopigmentary disorders are a varied group of pigmentary disorders that are common among Indians and Asians [1]. They produce whitening of the skin due to a decrease in melanin synthesis or the partial or complete absence of melanocytes [2]. Hypopigmented macules are reported in 1 out of 20 adults and children [3]. Generally, they are benign or nonspecific, posing a cosmetic or psychological challenge to the patient; rarely do they indicate underlying systemic disease or primary skin malignancies [4, 5].

As per recent studies, the disorders of hypopigmentation have been focused on a lot in the recent past due to the growing income status among Asians [6]. But the treatment of these disorders is manifold and depends on the cause of hypopigmentation; e.g., post-inflammatory hypopigmentation (PIH) becomes better after correcting the underlying condition, but in some conditions like leprosy, it's highly challenging to produce repigmentation even after the successful treatment of the infection. Vitiligo may need a multifactorial treatment approach that includes medical, physical (UV light), and surgical therapy [6]. Regardless of the different treatment modalities, it is often bothersome and disappointing for the patients as well as the physician [7]. According to Dogra *et al.*, it's difficult to treat these disorders since the pathophysiology of hypopigmentary disorders is still poorly understood [4].

A study done in western India states that despite the stigma caused by these disorders, especially in dark-skinned individuals, the quality of life (QOL) is often ignored in most routine management strategies [8]. Studies addressing the treatment pattern and the impact of QOL are very scarce in Indian literature. Hence, this research was conducted to study the treatment pattern and the impact of QOL among participants with hypopigmentary disorders.

MATERIALS AND METHODS

After receiving Institutional Ethics Committee approval (KIMS/IEC/9/10/2014), this prospective, observational study was conducted using purposive sampling among 48 newly diagnosed and treatment-naive participants with hypopigmentary disorders of the skin attending the dermatology outpatient department (OPD) of KIMS, a Tertiary Care Hospital and Research Centre, in Bangalore, Karnataka, India, for eighteen months. Written informed consent was obtained from the study participants after explaining the study procedure in detail in both English and vernacular language.

Participants of either gender who were newly diagnosed with hypopigmentary disorders, aged between 18 to 65 y, with or without comorbidities, and available for regular monthly follow-ups were included in the study. Those with congenital hypopigmentary disorders, neoplastic disorders of the skin, and pregnant and lactating women were excluded from the study.

A specially designed case record form (CRF) was used as a data collection tool (demographic and clinical data). The obtained data was analyzed to determine the drug utilization pattern (route of administration, therapeutic class of the drug, the drugs or drug combinations used, dosage form, frequency, duration of use), adverse events (AEs), and QOL. A 10-item questionnaire named the dermatology life quality Index (DLQI) was used for assessing QOL [9, 10]. Regular review visits were planned every month for three months to review the prescription pattern, AEs, and QOL.

The collected data was analyzed using descriptive statistics. An analysis of variance (ANOVA) was used for assessing DLQI. Statistical software (SPSS v20) aided in the analysis of data, and Microsoft Word and Excel were used to generate graphs and tables.

RESULTS

Overall, 48 participants enrolled in the study. Male participants had an average age of 36.69±15.58, while female participants had an average age of 40.96±11.88. The number of females was more (52%) than males (47.9%). The most prevalent disorder in our study was vitiligo (45.8%), followed by pityriasis versicolor (PV) (25%), as shown in table 1.

Table 1: Types of hypopigmentary disorders

S. No	Hypopigmented disorder	No of participant's n (%)
1	Vitiligo*	22(45.8)
2	Post-inflammatory hypopigmentation (PIH)†	6(12.5)
3	Idiopathic guttate hypomelanosis	3(6.25)
4	Pityriasis versicolor (PV)§	12(25)
5	Leprosy‖	5(10.4)
Total		48(100)

*Vitiligo vulgaris (n=12), Focal vitiligo (n=6), Acrofacial vitiligo (n=4), †Trauma (n=2), Psoriasis (n=2), Discoid lupus erythematosus and burns one each, §More common in males (n= 9), ‖It includes Multibacillary (n=4), Indeterminate type (n=1)

Mode of treatment

Topical administration was the most common mode of therapy in 31.25% of participants and included calcineurin inhibitors, antifungals, and growth factors. Among 41.66% of participants, topical therapy [calcineurin inhibitors (tacrolimus 0.1% ointment), topical antifungals, and basic fibroblast growth factor (bFGF) decapeptide lotion] plus systemic therapy [glucocorticoids (GCs), systemic antifungals, antioxidants, and newer antiepileptics] was used. A participant with lepromatous leprosy who suffered from erythema nodosum leprosum (ENL) was prescribed immunomodulators like thalidomide and newer antiepileptics like pregabalin and gabapentin. In 20.83% of participants with vitiligo, topical (bFGF decapeptide lotion)+systemic therapy (oral antioxidants)+phototherapy [narrow-band ultraviolet B radiation (UVB)]/photochemotherapy, which included the use of the drug Psoralen (tablet methoxsalen 10 mg) in conjunction with ultraviolet light A (PUVA) radiation, or Psoralen intake followed by sun exposure as a source of UVA (PUVAsol) was recommended. Topical therapy (Tacrolimus ointment, bFGF decapeptide lotion) and phototherapy (narrow-band UVB) were employed in 6.25% of participants with vitiligo.

Group of drugs

Calcineurin inhibitors (62.5%) were the most commonly prescribed group of drugs, followed by growth factors (54.1%) like bFGF decapeptide lotion. Antifungals (25%) were prescribed in PV. Melanizing agents (n = 9, 18.75%) like oral psoralen-methoxsalen 10 mg and systemic GCs (n = 7, 14.58%) like triamcinolone (low dose) were used to arrest rapidly spreading vitiligo and promote repigmentation. Antilepra drugs (n = 5, 10.41%) were used as part of multidrug therapy for leprosy. Vitamin D analogs (4.1%), like topical calcipotriol were prescribed in PIH due to psoriasis [table 2].

Table 2: Group of drugs

S. No.	Class of drugs	N (%)
1	Calcineurin inhibitors	30 (62.5)
2	Growth factors [Basic fibroblast growth factor (bFGF)decapeptide lotion]	26(54.1)
3	Antifungals	12(25)
4	Melanizing agents (Oral psoralen-methoxsalen10 mg)	9(18.75)
5	Systemic Glucocorticoids (GCs) (Triamcinolone 40 mg I. M)	7(14.58)
6	Antilepra drugs (Oral-Rifampicin 600 mg, Dapsone 100 mg, Clofazimine 300 mg)	5(10.41)
7	Vitamin D analogs and Combinations	2(4.1)

Calcineurin inhibitors, GCs and vitamin D analogs

[Table 3] enumerates calcineurin inhibitors, antifungals, vitamin D analogs, and others used either as monotherapy or fixed-dose combinations (FDCs), topical or systemic, curative or symptomatic. Calcineurin inhibitors like tacrolimus (60.41%) were the most commonly prescribed topical formulation as a melanizing agent along with either PUVAsol (oral methoxsalen 10 mg+ exposure to sunlight) or narrow-band UVB therapy in vitiligo. In participants with acrofacial vitiligo (n = 4, 8.3%), narrow-band UVB therapy, topical tacrolimus and topical bFGF was administered. Generally, phototherapy was administered twice weekly at a minimal erythema dose (MED) until repigmentation. In generalized vitiligo (>20% BSA involvement), narrow-band UVB therapy (n = 8, 16.6%) was the preferred first line in participants with co-morbidities like hypothyroidism and hepatic or renal disorders. A few individuals (n = 9, 18.75%) underwent PUVAsol therapy due to cost factors. The pattern of melanizing agents administered was growth factor (n = 26) in the morning and tacrolimus ointment at night. Growth factors were used as an adjuvant to GCs and PUVAsol or UVB in the case of focal vitiligo and other hypomelanoses, especially those in cosmetically important areas. In participants (n = 1, 2.8%), capsule cyclosporine 50 mg, a calcineurin inhibitor, and a combination of topical GCs and a vitamin D analogs, which act by reducing inflammation and keratinization, were prescribed to correct the underlying pathology in psoriasis with hypopigmented lesions.

Antifungals

Antifungals like capsule itraconazole 100 mg (n = 6, 12.5%) for 5 to 10 d; tablet fluconazole (n = 5, 10.41%) 150 mg once weekly for two to four weeks; ketoconazole cream and or soap (n = 12, 25%); and luliconazole (n = 1,2%) cream were prescribed as definitive therapy in PV. Oral antifungals were preferred in severe cases of PV [table 3].

Table 3: Individual medications

Drugs, Dose/concentration, route	N (%)*
Calcineurin inhibitors (n=30, 62.5%)	30
Tacrolimus (topical) 0.1%	29 (60.41)
Cyclosporine 50 mg, oral	1(2.08)
Antifungals (n=12, 25%)	
Fluconazole 150 mg oral	5 (10.41)
Itraconazole 100 mg oral	6 (12.5)
Ketoconazole 2% cream and soap	12 (25)
Luliconazole 1% cream	1 (2.0)
Vitamin D analogs and combinations (n=2,4.1%)	
Calcipotriol 0.005% topical	1 (2.08)
Calcipotriol 0.005%+Clobetasol 0.05% topical§	1 (2.08)
Others (n= 8, 16.6%)¶	

*n= Total number of participants receiving the particular class of drug; N= Number of participants receiving the individual drug. Topical medication is expressed as concentration and systemic as an individual dose; One or two antifungals were used as different formulation of same drug / different drugs of same class in one / same participant. §Vitamin D analogs+topical GC, ¶Participants with vitiligo (n=8), Narrow band UVB phototherapy was administered

Adjuvants

Oral antioxidants (n = 5, 10.41%) were used as adjuvants in vitiligo. Immunomodulators like thalidomide and systemic GCs (prednisolone) were prescribed for ENL in a participant with lepromatous leprosy. Newer antiepileptics (n = 2, 4.1%), like pregabalin and gabapentin, were prescribed for symptomatic relief of neuropathic pain associated with leprosy. Antihistamines (n = 6,12%) like levocetirizine and emollients, adsorbants, and

antioxidants (n=6,12.5%) were commonly prescribed as corrigents to provide symptomatic relief [table 4].

Table 4: Adjuvants

Name of drugs	N(%)*
Emollients, adsorbants, and antioxidants (n=6,12.5)	
Adsorbant+antioxidant	
Alovera+vitamin E	5(10.41)
Emollients (n=1,2.0%)	
Liquid paraffin	1(2.0)
Antioxidants (n=5, 10.41%)	
Oral antioxidants†	4(8.3)
Oral antioxidants+multivitamin‡	1(2.0)
Antihistamines (n=6, 12.5%)	
Levocetirizine 5 mg	6 (12.5)
Newer antiepileptics (n=2, 4.1%)	
Pregabalin+Gabapentin	2(4.1)
Others (n=1, 2.08%)§	

*n= Total number of participants receiving the particular class of drug; N= Number of participants receiving the individual drug, †Beta carotene 30 mg+Selenium200mcg+manganese 2 mg+copper1 mg+zinc sulphate 27.5 mg, ‡Omega-3 fatty acids 300 mg, vitamin C 250 mg, vitamin E 200 IU, zinc 12.5 mg, biotin 5 mg, lutein 5 mg, zeaxanthin 1 mg, copper 1 mg, selenium 75 mcg, §Immunomodulators like thalidomide (n=1) and systemic GCs (prednisolone) (n=1) were used to treat ENL

QOL

At the baseline visit, 62% of participants had DLQI scores ranging from 6–10 (a moderate effect on the participant's QOL), and at the third visit, 58% of participants had scores ranging from 2–5 (a small effect on the participant's QOL). The mean scores during the baseline and the third visit were 10.27±4.59 and 4.39±3.19, respectively. Also, the DLQI scores were higher in females (10.26±3.78) compared to males (8.61±3.45). DLQI scores from baseline to the end of the study (three months) and baseline to each visit were significant with **P<0.01 [fig. 1].

Changes to treatment

Among 3 (6.25%) participants, the most common reason for the change in treatment was AEs. Of these, 2 (4.1%) participants on methoxsalen complained of redness and burning (phototoxic reactions), which was discontinued for a week and restarted. 2% of participants undergoing phototherapy complained of phototoxic reactions, and they were advised not to apply bFGF during days of phototherapy. 2% of participants with systemic triamcinolone therapy complained of weight gain and gastritis; it was gradually stopped for symptomatic relief, and emollients and antihistamines were prescribed. One (2.08%) participant with vitiligo who was on topical tacrolimus and bFGF therapy was substituted with narrow-band UVB phototherapy due to an inadequate clinical response. In one participant (2.08%) with psoriasis, liquid paraffin was replaced by a less greasy emollient formulation due to cosmetic unacceptability.

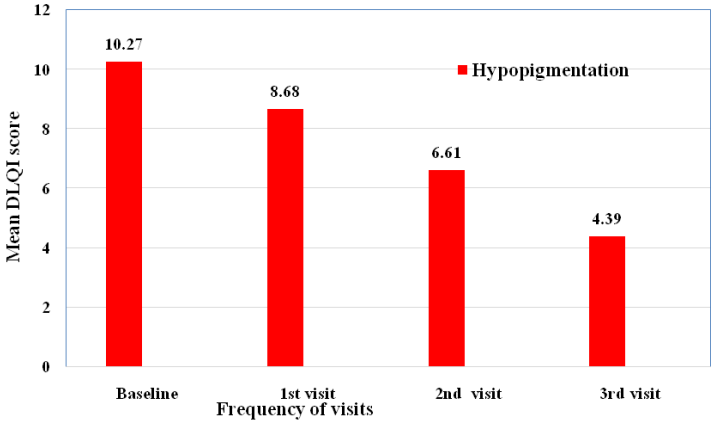

Fig. 1: Mean dermatology life quality index (DLQI) scores

AEs

AEs like acneiform eruption (n = 5, 10.41%), rosacea (n = 3, 6.25%), hypopigmentation (n = 2, 4.1%), hypertrichosis (n = 2, 4.1%), wrinkles (n = 1,2%), and telangiectasia (n = 1,2%) were commonly seen in participants who were on long-term topical GCs therapy (2nd visit, 2 mo). 16.6% and 4.1% of participants who were on long-term systemic triamcinolone complained of gastritis and weight gain, respectively. Sunburn and nausea were seen in one participant who was on phototherapy but disappeared on subsequent visits. 2% of participants taking Itraconazole complained of itching and nausea, and only one (2%) participant required hospitalization for lepra reaction. A causality analysis of AEs was not done.

DISCUSSION

In the present prospective observational study, the pattern of drug use in hypo pigmentary disorders, its AEs, and QOL was assessed in 48 participants attending the dermatology OPD at KIMS Hospital and Research Centre, Bangalore. It was found that the most common class of drug prescribed was calcineurin inhibitors, and the AEs were gastritis and acneiform eruptions. There was a significant improvement in QOL after treatment.

Male participants had a mean age of 36.69±15.58, while females had a mean age of 40.96±11.88. Females outnumbered males (n = 25) by a factor of two. The most prevalent disorder in our study was vitiligo, similar to other studies [1].

Topical therapy was the mainstay of treatment, of which calcineurin inhibitors (n = 30) were the most commonly prescribed class of drug, followed by growth factors (n = 26) like bFGF lotion, similar to a study by Renju and Singam *et al.* among participants with vitiligo [11, 12]. As per a study by Indraneel *et al.*, though topical mode was the most common modality of treatment in vitiligo, topical corticosteroids were more often preferred, closely followed by topical calcineurin inhibitors and bFGF lotion [13]. Antifungals (n = 12) were prescribed in PV, comparable to another study [14]. Melanizing agents (n = 9) like oral psoralen-methoxsalen (10 mg) and systemic GCs (n = 7) were prescribed to participants with vitiligo, in line with other research [15–17]. Antilepra drugs (n = 5) were used as multidrug definitive or curative therapy for leprosy, which was consistent with previous research [18]. Vitamin D analogs (n = 1) like topical calcipotriol were prescribed in PIH due to psoriasis; similar observations were seen in other studies [19–21].

Use of topical along with systemic agents (GCs, antifungals, antioxidants, newer antiepileptics like pregabalin and gabapentin, immunomodulators like thalidomide) and phototherapy (narrow band UVB), photochemotherapy (PUVAsol), or topical plus phototherapy (narrow band UVB) was in line with other studies [4, 15–17]. Though topical therapy forms the mainstay of management,

in a few studies, surgical modalities were also employed, which was not seen in our study since they were generally reserved for stable (at least 6 mo), medical treatment-resistant, and residual depigmented lesions, and in our study, the follow-up was only 3 mo, so such modalities of approach were not seen [4, 15].

Among the calcineurin inhibitors, tacrolimus (n = 29) was the most commonly prescribed topical formulation as a melanizing agent along with either PUVAsol (oral methoxsalen 10 mg+ exposure to sunlight) or narrow-band UVB therapy in vitiligo. In participants with acrofacial vitiligo (n = 4), narrow-band UVB therapy plus topical tacrolimus plus topical bFGF was administered, concurrent with other studies [17, 22]. Generally, phototherapy was administered twice weekly at a MED until repigmentation occurred, which was seen after three months, similar to another study [17, 22]. Parallel studies have stated that phototherapy is generally expensive, requires multiple sessions, and has frequent side effects [22].

Similar to other studies [15, 17, 19], in generalized vitiligo (>20% BSA involvement), narrow-band UVB therapy (n = 8) was the preferred first-line since it was considered to be safer in participants with co-morbidities like hypothyroidism, hepatic, or renal disorders compared to PUVA with less GI side effects and phototoxic reactions and required a shorter duration of therapy without post-treatment photoprotection. A few individuals (n = 9) underwent PUVAsol therapy due to financial constraints, similar to other studies [17, 22]. In participants (n = 1), capsule cyclosporine 50 mg, a calcineurin inhibitor, and a combination of topical GCs and a vitamin D analog, which act by reducing inflammation and keratinization, were prescribed to correct the underlying pathology in psoriasis with hypopigmentary lesions, as hypopigmentation can be reversed by treating the active lesions, as evidenced by another study [15, 19, 20].

The pattern of melanizing agents administered was growth factor (n = 26) in the morning and tacrolimus ointment at night (since photosensitivity was common), while in focal vitiligo, tacrolimus ointment was applied as a GCs-sparing agent, especially in cosmetically sensitive areas where GCs were contraindicated. Growth factors (n = 26) like bFGF decapeptide were used for the repigmentation of small patches of vitiligo and other hypomelanoses, especially those in cosmetically important areas. It was used as an adjuvant with GCs and PUVAsol or UVB to avoid the potential long-term effects of both, which were identical to other studies [15–17, 22, 24]. As per our research, low-dose triamcinolone intramuscularly was administered once a month to arrest rapidly spreading vitiligo and promote repigmentation. However, in a few studies on vitiligo, an oral mini-pulsed regimen containing dexamethasone was used [12].

Use of antifungals like capsule itraconazole (n = 6), tablet fluconazole (n = 5), ketoconazole cream and or soap (n = 12), and luliconazole (n = 1) cream as definitive therapy in PV (the fungal metabolite azelaic acid produces hypopigmentation) and preference towards oral antifungals in severe cases of PV were consistent with other studies [14].

Oral antioxidants (n = 5) were used as adjuvants in vitiligo, similar to other studies [15, 19, 22]. Immunomodulators like thalidomide and systemic GCs (prednisolone) were prescribed for ENL in a participant with lepromatous leprosy, like in other studies [25]. In other studies, newer antiepileptics (n = 2) such as pregabalin and gabapentin, were prescribed for symptomatic relief of leprosy-related neuropathic pain. Antihistamines (n = 6) like levocetirizine and emollients, adsorbants, and antioxidants (n = 6) were commonly prescribed as corrigents to provide symptomatic relief.

AEs like acneiform eruption (10.41%) due to topical GCs and gastritis (16.6%) and weight gain (4.1%) due to systemic GCs were identical to other studies [11]. As per Indraneel *et al.*, there were no AEs to the prescribed medication [13]. Similar reports of methoxsalen and phototherapy-induced redness and burning (phototoxic reactions) were reported in other analyses as well, and the AEs due to narrow-band UVB phototherapy were well tolerated and spontaneously disappeared a few hours after treatment in most cases [22]. Itraconazole-induced itching and nausea were comparable to other research [19]. Only one participant required hospitalization for a leprosy reaction.

The QOL based on the DLQI demonstrated a significant change in the available line of therapy. The significant impact on QOL among females also corresponds to other studies [8, 27].

CONCLUSION

The most common treatment modality was topical therapy; systemic and/or phototherapy were preferred to improve therapeutic outcomes. The most frequently prescribed drugs include calcineurin inhibitors and growth factors. Phototherapy (narrow-band UVB therapy) or photochemotherapy (PUVAsol) was considered only for vitiligo. The most common AEs observed were gastritis with systemic steroids and acneiform eruption with topical GCs, and there was an improvement in QOL after treatment. More Randomized control trials involving a larger number of participants on a larger scale for a longer duration, addressing the psychological impact of the disease as well, are required to further refine and formulate a guideline for improved outcomes.

LIMITATIONS

The sample size was relatively smaller with a short study duration. The treatment modalities were not compared in terms of efficacy, tolerability, safety, and cost. A causality analysis was not done.

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AUTHORS CONTRIBUTIONS

All the authors contributed to the concept, design, data collection, data analysis, interpretation, drafting of the article, critical revision of the article, and final approval of the version to be published.

CONFLICTS OF INTERESTS

The authors declare that there are no conflicts of interest regarding this article's research, authorship, and publication.

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