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DRUG UTILIZATION STUDY, ADVERSE EFFECT AND ASSESSMENT OF QUALITY OF LIFE IN VITILIGO PATIENT IN DERMATOLOGY DEPARTMENT OF A TERTIARY CARE TEACHING HOSPITAL

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ABSTRACT

Introduction: Vitiligo is a hypopigmentation disorder of skin where the loss of functioning melanocytes causes the appearance of white patches on the skin. Patients with vitiligo experience significant psychiatric morbidity. Depression, dysthymia, sleep disturbances, suicidal thoughts, suicidal attempts and anxiety have been found in those affected with vitiligo. Vitiligo can also lead to difficulties in forming relationships, avoidance of certain social situations, and difficulties in sexual relationship. **Materials and methods:** An observational, prospective study conducted in vitiligo patients at Tertiary care hospital. The study was conducted from January 2016 to April 2017. Patient's Socio demographic data were recorded. Disease related history, medical history, drug history, history of allergy, family history, personal history details of co-morbid conditions, adverse drug reactions were noted and Quality of life index score was calculated. **Result:** Majority of the patients were 22.3% from 21-30 years of age group, female (64.7%), married (57.6%), housewife (37.1%), educated up to higher secondary level (54.7%) and had hypertension (5.2%) as most common co-morbid condition.95.2% of the patients had no family history of vitiligo.87.7% of the patients had personal habit of vegetarian diet. Majority of patients had vitiligo vulgaris (50.4%), stable (50.4%) and 70.9% of patients had vitiligo on exposed area of body. **Conclusion:** This study shows that over-all prescribing trends in our set-up require formation of guideline which leads to more appropriate and rational use of medications in vitiligo patients.

KEYWORDS: Drug utilization study, Adverse effect, Vitiligo, Quality of life index.

INTRODUCTION

Vitiligo is a hypopigmentation disorder of skin where the loss of functioning melanocytes causes the appearance of white patches on the skin. Vitiligo affects 1% of the world population, but the prevalence has been reported as high as 4% in some South Asian, Mexican and American populations. Vitiligo can develop at any age, but several studies report that 50% of cases appear before the age of 16 to 20 years of age. 35% of patients with vitiligo experience significant psychiatric morbidity. Depression, dysthymia, sleep disturbances, suicidal thoughts, suicidal attempts and anxiety have been found in those affected with vitiligo. Vitiligo can also lead to difficulties in forming relationships, avoidance of certain social situations, and difficulties in sexual relationship.

Several systematic reviews assessing the clinical efficacy of topical corticosteroids, narrowband ultraviolet light B (UVB), psoralen with ultraviolet light A exposure (PUVA), calcipotriol, l-phenylalanine, topical immunomodulators (tacrolimus and pimecrolimus), excimer laser, and surgical therapy in vitiligo patients.[1]

MATERIAL AND METHOD

This was an observational, prospective study conducted in vitiligo patients at Tertiary care hospital. The study was conducted from January 2016 to April 2017 and was approved by Institutional Ethics Committee. Total 210 patients were enrolled in the study.

Patients of any age and either sex attending vitiligo clinic at tertiary care teaching hospital and diagnosed vitiligo by dermatologist and receiving treatment were included in the study.

Informed consent was obtained. Patient's Socio demographic data: Age, sex, marital status, education, occupation and socioeconomic class were recorded. Disease related history like chief complaints and origin, duration and progress. Past history like medical history, drug history and history of allergy. Family history of

vitiligo of the patient's personal history related with diet, smoking and alcohol. Details of co-morbid conditions like Diabetes, Thyroid disease and others. Details of adverse drug reactions were noted and Quality of life index score was calculated.

Case record files of the included patients were analyzed at every visit of the patients. Follow up was carried out for all patients monthly for 6 months. Quality of life index was taken in adult patients on first visit.

Dermatology life quality index was used as the specific index for assessment of quality of life in vitiligo patients. The questionnaire consisted of 10 questions with a six-point like symptoms and feeling, Daily activity, Leisure at work and school, Personal relationships and treatment. The data collected were analyzed using descriptive percentage base statistic.

RESULT

The analysis of the demographic characteristics presented in table1, revealed that majority of the patients involved in vitiligo belonged to the age group of 21-30 years(22.3%),majority of female 136(64.7%),and housewives by occupation 78(37.1%) most of them were educated up to higher secondary 115(54.7%)majority of patients were married 121(57.6%) and belongs to lower socio economical class 193(91%) ,family history was absent in 200(95.2%) patients, most common addiction was tobacco chewing in 8(3.8%) patients, majority of patients having vegetarian diet habit 184(87.7%).

Table: 1. Socio demographic details.

Socio demographic profile		**Number of patient(%)(n=210)**
Age group	21-30	47(22.3%)
Gender	Female	136(64.7%)
Education	Higher secondary	115(54.7%)
Occupation	Housewife	78(37.1%)
Marital status	Married	121(57.6%)
Socio-economical class	Lower socio-economical class	193(91.9%)
Family history	Absent	200(95.2%)
Addiction	Tobacco chewing	8(3.8%)
Diet history	Veg diet	184(87.7%)

Table: 2. Disease profile.

Disease profile		**Number of patients (%) (n=210)**
Type of vitiligo:	Vitiligo vulgaris	106(50.4%
Progression of vitiligo	Stable	106(50.4%)
Exposed /covered area of body	Vitiligo over exposed area	149(70.9%)
Co-morbid conditions	Hypertension	11(5.2%)

According to type of vitiligo majority of patients had vitiligo vulgaris106(50.4%) and progression of vitiligo majority was stable type106(50.4%), and majority of patient had vitiligo on exposed part of the body 149(70.9%).Most common comorbid condition was hypertension 11(5.2%)(table no:2)

Table 3A: Oral therapy.

Type of drugs	**No. Of Patient (%)**
Anti-oxidant +Multivitamins	189 (92.1)
Corticosteroids	13(6.1)
Others	3(1.4)
Total	205

92.1% of patients received micronutrient oral medication apart from topical therapy. Only 6.19% received oral steroid therapy additional to topical therapy and 1.4% patients received other therapy like Ayurveda treatment which shown in table: 3A.

Table: 3B Topical therapy.

Drugs	Type of Drugs		Patients (%)
Single (n=153)	corticosteroid	Betamethasone	119(56.6)
		Clobetasol	20(9.5)
		Momentasone	11(5.2)
	Single immunosupprant	Tacrolimus	3(1.4)
Combination of two drugs (N=47)	Two corticosteroids	Betamethasone+Clobetasol	16(7.6)
		Betamethasone+Momentasoe	21(10)
		Clobetasol+Momentasone	2(0.9)
	Corticosteroids+ Immunosuppressant	Betamethasone + Tacrolimus	7(3.3)
		Clobetasol+Tacrolimus	1(0.4)
Combination of three drugs	Corticosteroids +Immunosuppressant +Placental extract	Momentasone+Tacrolimus+ Placental extract	1(0.4)
	Total		201(95.7)

Most of patients received single topical agent (71.42%), among them most common drug was corticosteroid. Single topical corticosteroid most commonly prescribed was betamethasone (56.66%) while two corticosteroid combinations was prescribed in 18.57% cases. Only 1.4% patients receive topical immunosuppressant and 3.33% patient were prescribed combination of topical steroid and immunosuppressant. Only single patient received three drug combinations which shown in table 3B.

PHOTOTHERAPY: 38 (18%) of study patients received phototherapy.

Interpretation of quality of life index score

Among 210 patients 42 were paediatric so they had been excluded from quality of life index.so these interpretation was done on adult population only. In stigma and behaviour Overall, 31-40 years age group had poor quality of life then other groups(18.4%), women(12.5%) had poorer QOL (higher QoL scores) than men, Educated peoples are more affected(14.8%),Patients who had vitiligo on exposed part of body had poorer quality of life index then covered part of body(13.6%).

Quality of life index shows that 10.71% vitiligo patients had small effect 3.3% patients had moderate effect and in 4.16% had severe effect on their life their life.

Table 4: WHO prescribes core indicators?.

Prescribing Indicators	Value
Average number of drugs per prescription	2.29 (481/210)
Percentage of drugs prescribed by generic name	99.58 %
Percentage of patients prescribed antibiotics	0%
Percentage of patients prescribed injectable medicines	0 %
Percentage of drugs prescribed from National list of essential medicine	66%(321/481)
Percentage of drugs prescribed from WHO essential list of medicine	28%(137/481)

Average number of drugs prescribed per encounter was 2.29drugs.99.58% of drugs prescribed by generic name of drugs.

28% of the prescribed drugs were from WHO model list of essential medicines, 20th edition (updated) March 2017 and according to National list of essential medicines, India, 4th edition[s], 2016, 66 % of prescribed drugs were essential drugs.

DISCUSSION

Vitiligo is a hypopigmentation disorder where the loss of functioning melanocytes causes the appearance of white patches on the skin. Considering demographic profile, the age of onset for vitiligo commonly begin in childhood or young adult hood, with peak onset of 10 to 30 years. But it may occur in any age.[4] these findings are similar with our result where range age of onset was 0-70 years but peak onset of age is 21-30 years. Similar results were seen with a study done by Vora R et al.[25] were majority of cases are of 21 to 30 age group. Whereas contrasting results were seen in another studies, Shah H et al.[26] were 32.87% of cases were in 11-20 age group and Fahaad H A et al.[27] were 28.7% of cases were in 31-40 age group.

Both sexes are equally affected. A female preponderance has been reported but discrepancy has been attributed to cosmetic concerns by female patient.[4] in our study also female dominancy was seen (64.7%). The female to male

ratio was 1.8:1. This was similar with a study done by Shajil E M et al.[28] were 61.56% of patients were female. Shah H et al.[26] also reported similar female preponderance 68.4%. On contrary, Fahaad H A et al.[27] reported male preponderance 57.4%.

In our study, 54.75% patients were educated up to higher secondary level, similar results were seen in a study done by Shah H et al.[26] were 41.36% of patients were educated up to higher secondary level. Occupation perspective, in our study majority were housewives 37.1%**.** Similar results were shown by a study done by Fahaad HA et al.[27] were 24.8% of patients were housewives. However, another study done by Shah H et al.[26] reported 41.09% to be students.

Most of the patients were from lower socio economic class. Reason for this is that, the study was done in Government medical college, where majority of patients come from rural areas.Familial occurrence has been reported to vary from 5 to 30% in different studies. Human leucocyte antigen (HLA) type significantly related to family history and early onset of vitiligo.

Positive family history is considered to be a poor prognostic factor.[25] in our study, 4.7% had positive family history. Fahaad HA et al.[27] also reported 5.9% of positive family history. Another study done by Shajil E M et al.[28] reported about 21.93% of patients with positive family history.

Vitiligo is associated with many systemic as well as cutaneous disorders, among them hypertension, diabetes and thyroid dysfunction are common. Co-morbid conditions were associated with 4.7% of total patients in our study. Hypertension (5.2%) occurs in majority of cases followed by diabetes mellitus and thyroid disease. Similar results were seen in study done by Shah H et al.[26] were co morbid conditions were seen in total 4.56% of patients with hypertension (0.55%). Another study done by Shajil E M et al.[28]also reported 6.13% association of vitiligo with positive family history.

Addiction history was positive in very few (4.2%) of cases in our study. This was in consonance with a study done by Singh S et al.[29] who stated that there is no association between addiction and vitiligo. Fahaad HA et al.[27] also reported 5% of patients with addiction history. Vitiligo was found to be associated with deficiency of Vitamin B12 and people on vegetarian diet are Vit B12 deficient.[30] 87.7% of study participants in our study were vegetarian, similar results were seen in a study done by Vora R et al.[25] (91.3% vegetarian).

In our study according to type of vitiligo, Vitiligo vulgaris (50.4%) was most common followed by acrofacial, focal and mucosal vitiligo. Similar result was seen with a study done by Vora R et al.[1] and Shajil EM et al.[2]Majority of the patients had stable vitiligo at the time of presentation. However, another study done by Shah H et al.[3] reported majority to have progressive vitiligoExposed part of body was more affected (70.9%), which may impair quality of life and is associated with increased rates of psychological disorders. A study done by Fahaad HA et al.[4] also stated the similar result.

Considering treatment part, principal approach involves topical monotherapy. Involving either topical corticosteroid or an immunosuppressant.71.4% of patients were on corticosteroid topical therapy which includes Betamethasone, Clobetasone and Momentasone. Another topical therapy, observed in our study was that of Tacrolimus as immunosuppressant. Monotherapy with Tacrolimus is seen in only 1.4% of patients. This could be explained as it is an expensive therapy and is not available in government supply. Regarding oral drugs, Vitamin B12 (86%) was commonly prescribed. This was similar with a study done by Juhlin L et al.[5] Some of the patients in our study were prescribed oral corticosteroids as pulse therapy where oral 5mg betamethasone/dexamethasone was given for 2 consecutive days per week. Similar pulse therapy was seen in another study done by Parisch S et al.[6]

In present study, 18% patients were on ultra violate narrow band therapy. It is an effective and safe therapeutic modality. Treatment with narrowband UVB (311nm) is considered first-line option for extensive vitiligo. A study done by Kumar YH et al.[7] reported 97% of repigmentation with narrow band UVB.Various adverse drug reactions (11.6%) were encountered like generalized weakness and hyper acidity, photosensitivity, hypertrichosis and hyperpigmentation are observed due to topical application. Similar findings were seen with a study done by Gupta AK et al.[8]

Vitiligo can be a psychologically devastating disease which has a significant impact on quality of life (QOL).In our study out of 168 patients 4.10% with vitiligo experienced very large effect on their life. Moderate effect on life was noted in 3.5% of patients and 10.7% patients had small effect on life. However Mishra N et al.[9] reported that significantly higher rate (26%) of patients were affected by the disease. Young adult patients had poorer quality of life. The patients of 30–40 year age group experienced the more effect than other age group. Similar results were seen with study done Mishra N.et al.9 and Dolatshahi et al.[11] 16% female are affected as compared to 2.2% of male patients. This result was compatible with study done by Dolatshahi et al.[10] Educated patients are more prone to affect as compared to illiterate people, Our result shows that 14.8% educated which contrast to result of study is done by Hedayat et al.[11] It may be due to they are more aware about disease and social stigma. Quality of life index showed vitiligo over exposed part is 13.6% as compared to covered part of body. Which is compatible with the study done by Hedayat et al.[11] and contrast to study done by Dolatshahi et al.[10]

Total number of drugs per encounter was 2 drugs per encounter. On an average 2.29 drugs per encounter were prescribed, 99.58% of drugs were prescribed by generic name. 66% of the drugs were prescribed from the National Essential Medicines List (2015)[12], 28% drugs were prescribed from the WHO Essential Medicines List (2017).[13] Most of the orally prescribed drugs were included in Essential list but many of the topical ones prescribed during study period were not mentioned in either of the two lists which include Momentasone, Clobetasone and Tacrolimus.

SUMMARY

Majority of the patients were 22.3% from 21-30 years of age group, female (64.7%), married (57.6%), housewife (37.1%), educated up to higher secondary level (54.7%) and had hypertension (5.2%) as most common co-morbid condition. 95.2% of the patients had no family history of vitiligo.87.7% of the patients had personal habit of vegetarian diet. Majority of patients had vitiligo vulgaris (50.4%), stable (50.4%) and 70.9% of patients had vitiligo on exposed area of body.

Topical corticosteroids (72.8%) were most commonly prescribed. Orally antioxidant and multivitamins were most commonly prescribed (92.1%) and corticosteroids were prescribed in 6.1% of patients. Majority of the patients received topical corticosteroids as mono therapy (72.8%) and among combination therapy steroids with immunosuppressant (3.7%), steroids with immunosuppressant and placental extract (0.4%) were prescribed. 18% patients received narrow band ultra-violate rays therapy. Most common adverse drug reaction was generalized weakness (4.7%) due to oral steroid therapy. Quality of life index is affected for about 18.4% in 31-40 yrs age group, 14.8% in educated, 12% in female and 13.6% of patients with having vitiligo in exposed area of the body. Total number of drugs per encounter in our study was 2.29 drugs per encounter, 99.58% of drugs were prescribed by generic name, 66% of the drugs were prescribed from the National Essential Medicines List (2015) and 28% drugs were prescribed from the WHO Essential Medicines List (2017).

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CONFLICTS OF INTEREST

There are no conflicts of interest.

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