Study of Drug Use Pattern & Analysis of Quality of Life In Patients of Acne Attending The Dermatology OPD In A Tertiary Care Hospital

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Abstract: Background: Acne vulgaris is a skin condition affecting a large proportion of the population. Various drug therapies are available for the same, which include topical and systemic drugs. Additionally, this disease has a profound impact on the quality of life (QOL) and hence this study was conducted with the aim of evaluating the drug use pattern as well the quality of life in such individuals. Aims: To study the drug utilization pattern of Acne vulgaris in Out Patient Department of Dermatology in a tertiary care hospital. To analyze health related Quality of Life using the Dermatology Life Quality Index (DLQI) and the Cardiff Acne Disability Index (CADI) Methods: (including settings and design and statistical analysis used) This was a prospective, cross sectional study of 8 weeks duration, which was approved by the Indian Council of Medical Research (ICMR). It was carried out on the patients visiting the Dermatology OPD at a tertiary care hospital who were diagnosed with acne for at least one month. The responses of patients were recorded by using the CADI and the DLQI questionnaires that addressed various aspects of QOL. The drug utilization pattern was also studied. The data was analyzed using the SPSS 22 software. The Spearman rho test was applied. Results: Mean age of the patients was 20.23 ± 2.78 years with male: female ratio 0.69:1. Majority of the patients were diagnosed with grade 2 acne vulgaris. A total of 389 drugs were prescribed to 90 patients. The number of drugs received by each patient was 4.32. The most commonly prescribed topical drug in this sample was clindamycin phosphate, which formed 26.83% of the total topical drugs. Among the systemically prescribed drugs, azithromycin was the most commonly used. The Cardiff Acne Disability Index and the Dermatology Life Quality Index was used to determine the Quality of Life of patients suffering from acne vulgaris. The mean CADI score was 6.34 ± 3.625. It was noted that the highest score was 21 and was scored by patients of the age group 21 to 23 years. The mean DLQI score was 9.02 ± 5.821, indicating that acne vulgaris moderately affects the health related quality of life of the patients. From the survey, it was observed that the highest score was 26 obtained from patients of the age group 18 to 20 years. Limitations: The study has limited sample size of 90 patients. Hence, entire spectrum of the disease and QOL correlation will not be robust. The correlation of improvement of QOL scores with therapy of acne could not evaluated. As it was a prospective, single point study, of limited duration, the improvement in the quality of life of the patients suffering from different grades of acne vulgaris, could not be assessed. Conclusions: The drug use pattern indicated that topical drugs formed a greater part of the treatment plans as compared to systemic drugs. Our study has also described the impact of acne on Quality of Life. Hence, dermatologists should be encouraged to add Quality of Life evaluations for patients with acne, since these might reveal a new facet of the disease, that is, its psychosocial impact and help intervene with more individual specific interventions. [K Chandani Natl J Integr Res Med, 2018; 9(1):108-116]

Key Words: Acne, Quality of Life, CADI, DLQI, Drug Utilization Pattern

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Introduction: Acne vulgaris, or simply known as acne is a skin condition characterized by black heads (open comedones), white heads (closed comedones), pimples, greasy skin and scarring. Severity of acne is divided into four grades, with grade 1 being the mildest and grade 4 being the most severe form of it.[1]

Skin diseases like acne are very common especially in the adolescent age group and form a large portion of the workload in the OPD. There are many drugs available for the treatment of acne that are administered both topically and systemically like the antimicrobials, vitamin A analogues (retinoids; isotretinoin) & hormonal preparations. Therefore, auditing of prescriptions related to the disease is essential to increase the therapeutic efficacy and to decrease the side effects & also to provide feedback to the prescribers. The main aim of this drug utilization research is to facilitate rational drug use. Without the precise knowledge of how drugs are being prescribed it is difficult to improve prescribing habits.[2] Considering the economic burden of the skin diseases, owing to its high prevalence, it is of interest to study the drug prescribing patterns. Periodic auditing of prescriptions is essential to increase the therapeutic efficacy, decrease adverse effects and

provide feedback to the prescribers. Drug utilization studies are useful for obtaining information about drug use pattern. Such analysis improves the standard of medical treatment at all levels in the health system.Since data about drug use for acne in Indian population is lacking, the present study is planned.

But there's more to this condition than that is perceived by the clinician. It is a currently accepted fact that evaluation of the severity of any disease should include not only the clinical factors but also the psychological & social factors. Despite availability of various treatments for acne, it persists as an issue, which has a profound negative impact on the Quality of Life (QoL) as pointed out by numerous studies.[3] This includes lowered self-esteem, maladjustment, depression, and anxiety, self consciousness accompanied by obsession. Younger patients may tend to be more susceptible to the adverse psychotic effects due to stigmatization and teasing. However adults aren't spared either. Adult patients with acne have higher unemployment rates comparatively and this further aggravates the problem of mental trauma.[4] Moreover, suicidal thoughts may become prevalent. Consequently, the psychosocial suffering of the patient may be neglected. Furthermore, there is a paucity of Indian studies in this field. Hence the QoL evaluation becomes the requirement of the study.

This study uses two renowned questionnaires that are aimed at analysing the psychosocial impact along with the effect on professional life, due to the skin disease. The advantage that these questionnaires provided was that they were simple for the patient to comprehend as the questions were self-explanatory and provided results that were valid and reproducible.

In order to observe the drug use pattern in the treatment of acne vulgaris, a case record form was utilized. This simple instrument recorded demographic data like name, age & sex, along with details of the drugs prescribed which included the dose frequency & duration of the treatment.

The number of drugs prescribes per prescription based on the currentrecommendations should not be more than two drugs. But it has been observed in several studies that the number of drugs per prescription exceed the recommendation and polypharmacy is commonly observed[5].

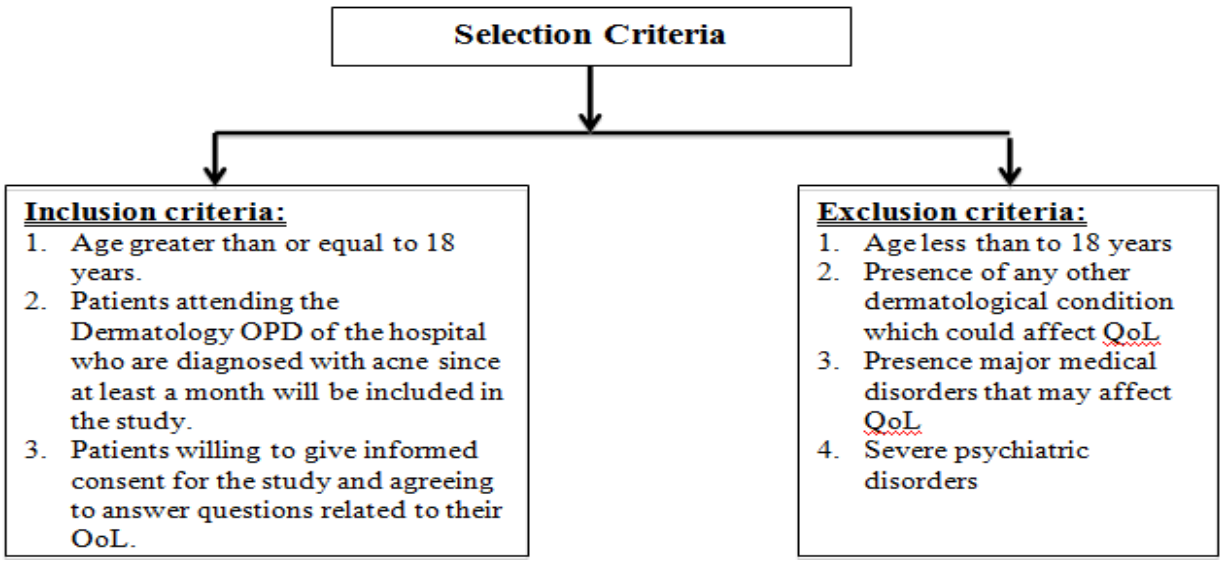
A study on the drug utilization pattern in the treatment of acne vulgaris was carried out in a tertiary care teaching hospital in Uttarakhand, India[6]. This study observed the trend of oral and topical drugs in the prescription of 238 patients. Our study followed a similar format except for the difference in the size of the sample. This study however, additionally looked into the distribution and prescribing trends of fixed dose combinations.

Another study was carried out in Bhubaneswar, Odisha, where the grading of acne was done using the same guidelines as used in our study. Also, the drug utilization pattern was analyzed similarly[7].

With regard to Quality of life analysis, a number of studies have been carried out outside of India. A study carried out in Sarawak, Malaysia used the Dermatology Life Quality Index (DLQI) to assess the Quality of Life among patients of acne above 16 years of age[8]. Similarly, a study was performed on 70 patients with acne vulgaris in Iran[9]. Inclusion criteria include having acne vulgaris and being over the 16 years. Exclusion criteria include having skin diseases different from the acne vulgaris, having a chronic disease, which would have an effect on QOL, or having apparent disability.

CADI is a questionnaire which is specific for acne and contains 5 questions –related to the last month about feelings, interference with social life and interaction with the opposite gender, avoidance of public places, appearance of the skin and perceived severity of disease state. Each question is scored from 0-3 leading to a total score of 0-15. A higher score shows a very large impact on quality of life[10].

Methods: The study began after obtaining permission from the Indian Council of Medical Research & the Institutional Ethics Committee. The approval of the hospital superintendent was taken & a written consent of each patient was obtained in their vernacular language. Consenting patients were given the questionnaire and informed that their participation is entirely voluntary and that they can drop out of the study at any given point of time. Moreover, the confidentiality of the data was maintained. Male and Female patients were enrolled irrespective of their ethnicity. However, selection criteria was applied:



Study Design: This was a prospective, unicentric cross sectional study of 8 weeks duration and was carried out on the patients visiting the Dermatology OPD at a tertiary care hospital who were diagnosed with acne for at least one month.

The responses of patients with various grades of acne were recorded by subjecting them to two questionnaires that was filled out by them. In case of illiterate patients, questions were asked orally. These instruments assessed the various aspects of quality of their life including psychological, social and occupational faces.

This instrument consists of two questionnaires:
a) The Cardiff Acne Disability Index
b) Dermatology Life Quality Index

The Cardiff Acne Disability Index[10] consists of 5 questions that assess the patient's attitude towards the condition. Each question consists of four options and each question is graded with a maximum score of 3 and a minimum of 0. The CADI score is calculated by summing the score of each question resulting in a possible maximum of 15 and a minimum of 0. The higher the score, the more the quality of life is impaired.

The English & Hindi versions of the CADI were used in accordance with the patient's choice of language.

The Dermatology Life Quality Index[11] is a simple 10-question validated questionnaire that examines the effect of the skin problem on the patient's social and work life in the past one week. The questionnaire is available in three vernacular languages; Hindi, Gujarati & English. It is self-explanatory and can be handed to the patient for filling. The DLQI questionnaire is designed for use in adults.

Scoring:

Table 1:

Option	Score
Very Much	3
A Lot	2
A Little	1
Not at All	0
Not Relevant	0
Question not answered	0
Question 7: "prevented work or studying"	3

The maximum score can be 30 and the minimum can be zero. The higher the score more is the QoL impaired. This resembles the CADI.

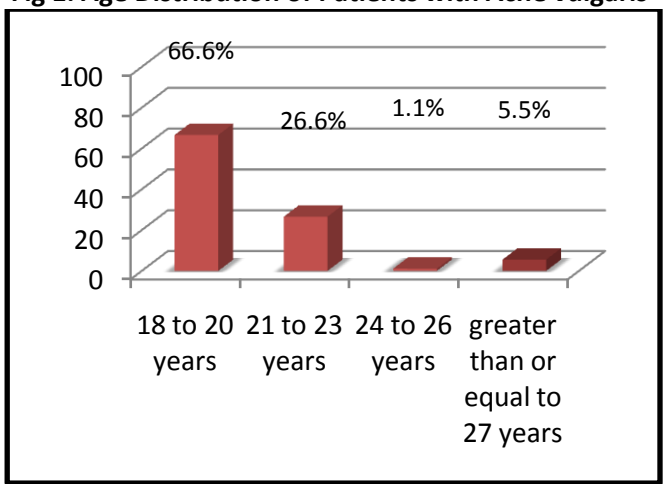
Meaning of DLQI Scores
0-1 = no effect at all on patient's life
2-5 = small effect on patient's life
6-10 = moderate effect on patient's life
11-20 = very large effect on patient's life
21-30 = extremely large effect on patient's life

Statistical Analysis: The data was entered in Microsoft Excel 2010 and analyzed using the SPSS 22 software. The Cronbach's Alpha test and Spearman rho tests were applied. Pearson Chi Square test was used to establish the correlations.

Results: Mean age of the patients was 20.23 ±2.78 years with the age group being 18-35 years.

Out of the 90 patients participating in the study, 60 belonged to the age group of 18-20 years.

Fig 1: Age Distribution of Patients with Acne vulgaris



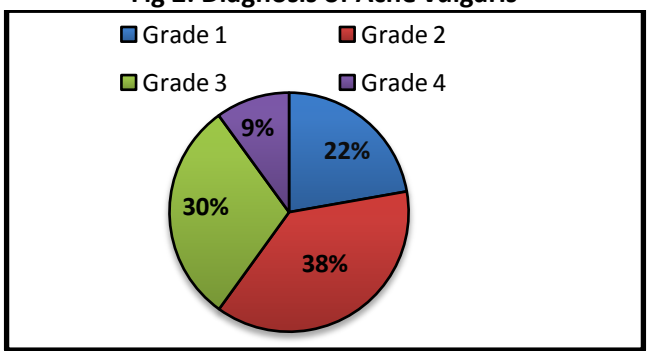
Male: Female ratio was 0.69:1, indicating preponderance of acne vulgaris among females.

Table 2: Duration of Acne Vulgaris among Patients

Duration of Acne (in months)	Number of Patients	Percentage % (Out of 90)
1 to 25 months	76	84.4%
26 to 50 months	7	7.7%
51 to 75 months	6	6.6%
Greater than 76 months	1	1.1%

84.4% of the patients were suffering from acne for 1 month to two years, while only 1.1% suffered for more than 6.3 years.

Fig 2: Diagnosis of Acne vulgaris



The bulk of the patients, i.e.; 37.7% that makes up almost 2/3rd of the study sample, were diagnosed with grade 2 of acne vulgaris.

Drug Use Pattern: A total of 389 drugs were prescribed to 90 patients over a span of 8 weeks, with more than 3/4th being topical and the rest being oral. The number of drugs received by each patient was 4.32.

Fig 3: Routes of Drug Administration

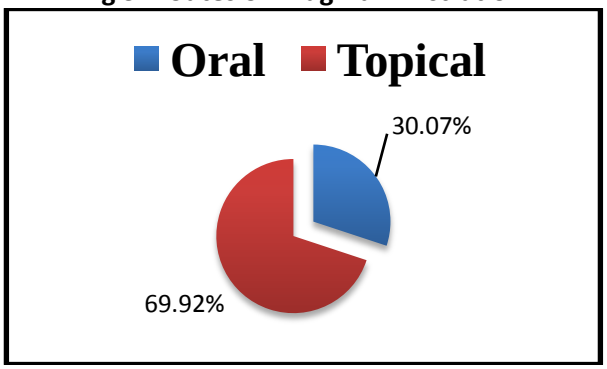


Table 3: Topical Drugs

Name of Drug	Frequency	%
Clindamycin Phosphate	73	26.83%
Salicylic Acid Face Wash	66	24.26%
Adapalene	36	13.24%
Benzoyl Peroxide	22	8.09%
Isotretinoin	19	6.99%
Nicotinamide	18	6.62%
Others	38	13.97%
Total	272	100%

Others: Aloe vera, Betamethasone Valerate, Calamine, Soap, Ketowash shampoo, Contratubex Cream, Clear Gel, Epiduo Gel, Fair eye Cream, Moiz Cleansing Lotion, Photoblock Sunscreen, Vera Lotion, Veracal Lotion, Vera moisturizer, Bilumina Cream, Lipiz Cream

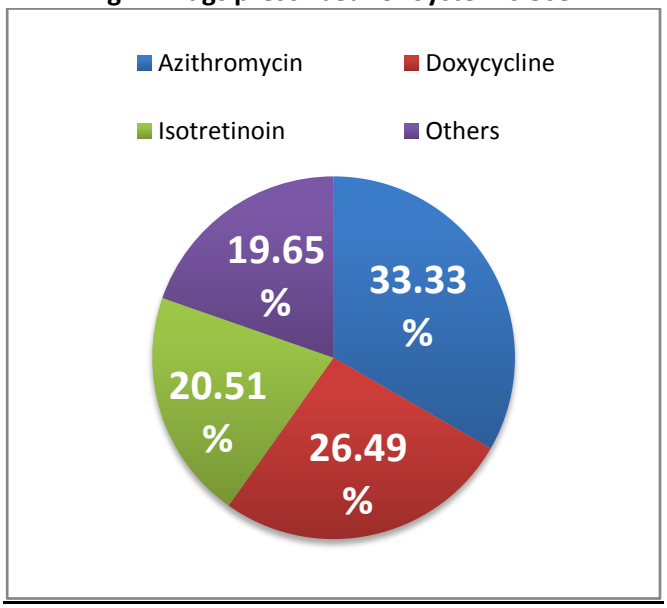
The most commonly prescribed topical drug in this sample was clindamycin phosphate, which formed 26.83% of the total topical drugs. The next most prescribed topical preparation was a salicylic acid face wash, which formed 24.26% of the topical drugs. This was followed by the vitamin A analogue, Adapalene, which formed 13.24% of the total topically prescribed drugs.

Table 4: Systemic Drugs

Generic Name of Drug	Frequency	%
Azithromycin	39	33.33%
Doxycycline	31	26.49%
Isotretinoin	24	20.51%
Others	23	19.65%
Total	117	100%

Others: Ascorbic Acid, Pheniramine Maleate, Ranitidine, Multivitamin B Complex, Chlorpheniramine Maleate

Fig 4: Drugs prescribed for Systemic Use



Among the systemically prescribed drugs, azithromycin formed a bulk of the prescriptions as it was prescribed to one third of the patients of different grades of acne.

Doxycycline followed as it formed 26.49% of the total 117 systemically prescribed drugs.

Quality of Life: The health related Quality of Life was assessed in 90 patients using two reliable questionnaires, the Dermatology Life Quality Index (DLQI) and the Cardiff Acne Disability Index (CADI).

The mean DLQI score was 9.02 ± 5.821, indicating that acne vulgaris moderately affects the health related quality of life of the patients. From the survey, it was observed that the highest score was 26 obtained from patients of the age group 18 to 20 years.

The lowest score was 0 which translates as no impact of acne on the quality of life. This score was noted in the patients belonging to the age group of 18 to 20 years.

Table 5: DLQI Score of patients with different grades of Acne Vulgaris (n=90)

Questions	Mean ± SD
Symptoms and Feeling	1.18 ± 0.881
Over the last week, how itchy, sore, painful or stinging has your skin been?	
Over the last week, how embarrassed or self conscious have you been because of your skin?	1.31 ± 0.967
Daily Activities	
Over the last week, how much has your skin interfered with you going shopping or looking after your home or garden?	0.76 ± 0.928
Over the last week, how much has your skin influenced the clothes you wear?	0.93 ± 0.922
Leisure	1.17 ± 0.997
Over the last week, how much has your skin affected any social or leisure activities?	
Over the last week, how much has your skin made it difficult for you to do any sport?	0.96 ± 3.225
Work and School	1.07 ± 1.225
Over the last week, how has your skin prevented you from working or studying?	
If no, over the last month, how much has your skin prevented you from working or studying?	0.74 ± 0.868
Personal Relationships	
Over the last week, how much has your skin created problems with your partner or any of your close friends or relatives?	0.74 ± 0.868
Over the last one week, how much has your skin caused any sexual difficulties?	0.61 ± 0.874
Treatment	
Over the last week, how much of a problem has the treatment for your skin been, for example, by making your home messy, or by taking up time?	0.62 ± 0.886
Total	9.32 ± 6.479

The mean CADI score was 6.34 ± 3.625. It was noted that the highest score obtained during the survey using CADI was 21 and was scored by the patients of the age group 21 to 23 years. The lowest score was 0, indicating that acne vulgaris had no impact on the quality of life. This score belonged to the age group of 18 to 20 years.

Table 6: CADI Score of patients with different grades of Acne Vulgaris (n=90)

Questions	Mean ± SD
1. As a result of having acne, during the last month have you been aggressive, frustrated or embarrassed?	1.38 ± 0.967
2. Do you think that having acne during the last month interfered with your daily social life, social events or relationships with members of the opposite sex?	1.17 ± 1.008
3. During the last month have you avoided public changing facilities or wearing swimming costumes because of your acne?	0.61 ± 0.817
4. How would you describe your feelings about the appearance of your skin over the last month?	1.54 ± 1.007
5. Please indicate how bad you think your acne is now:	1.71 ± 1.408
Total	6.34 ± 3.625

Correlation: The Spearman rho value is 0.676 at the significance level of $p < 0.0001$ ($p=0.000026$).

The Cronbach's Alpha value of the Cardiff Acne Disability Index (CADI) is 0.703 & that of the Dermatology Life Quality Index (DLQI) is 0.813.

Discussion: Acne vulgaris, or simply known as acne is a skin condition characterized by black heads (open comedones), white heads (closed comedones), pimples, greasy skin and scarring. There are four main interacting factors in the pathogenesis of acne vulgaris [12].

a) Increased sebum production,
b) Microbial flora changes,
c) Abnormal keratinization,
d) Inflammation

This study was carried out on 90 consenting patients visiting the Dermatology Outpatient Department at a tertiary care hospital, who were diagnosed with different grades of acne. Moreover it was a requirement that the patients involved in the study should be suffering from the skin condition for at least one month. Furthermore, it was mandatory that the participating patients did not suffer from any other health condition or psychiatric disorder that would affect their health related quality of life.

It was observed that the male: female ratio is 0.69:1, indicating a preponderance of the disease among females which is similar to a study carried out in South India wherein the male: female ratio was 0.68:1. This also resembles the gender distribution observed in a study carried out in Uttarakhand where the male: female ratio was 1:1.07[6].

The age group of the patients participating in the study was 18 to 35 with the mean age being 20.23 ±2.78 years in contrast to that of a study carried out in Malaysia wherein the age group was 23.7 ± 6.24 years [8]and to that of an Indian study where the mean age was 21.67 ± 0.51 years[6].

In our study, acne was graded as Grade 1,2 3 and, 4, based on the severity which is similar to the grading of acne applied in the study carried out at Department of Dermatology, Sexually Transmitted Disease and Leprosy, A. J. Institute of Medical Sciences, Kuntikana, Mangalore, Karnataka, India [13].

Table 7: Grading of Acne

Acne Grading	Clinical Features
I	Comedones, occasional papules
II	Papules, Comedones & few pustules
III	Predominant pustules, nodules, abscesses
IV	Many pseudo cysts, abscesses & widespread scarring

84.4% of the patients were suffering from acne for 1 month to two years, while only 1.1% suffered for more than 6.3 years.

Drug Use Pattern: Irrational prescription of drugs is a common occurrence in clinical practice. The cost of such irrational drug use is enormous in developing countries in terms of both scarce resources and the adverse clinical consequences of therapies that may have real risks but no objective benefits. Therefore periodic auditing of prescriptions is essential to increase the therapeutic efficacy, decrease adverse effects and provide feedback to prescribers[14].

Acne management is a long-term treatment and requires patience. The patient should be informed on the issue [16]. The drugs prescribed per patient were 4.32, which is quite similar to the number observed in Uttarakhand, that is, 4.76 drugs per prescription.[6]

A total of 389 drugs were prescribed to 90 patients over a span of 8 weeks, with more than 3/4th being topical and the rest being oral which is in contrast to the observation of a study carried out in Odisha where both oral (47.44%) and topical (52.56%) preparations were equally prescribed.[7] This difference of distribution might be explained by the fact that the sample size of the study was enormous as it contained the analysis of 1210 prescriptions as compared to our study that analyzed 90 prescriptions.

Our study revealed that Clindamycin phosphate is the most commonly used topical agent for the treatment of acne vulgaris. It formed 26.83% of the total topically administered drugs. A similar observation was made by the Malaysian study.[8]Although clindamycin phosphate is inactive in vitro, rapid in vitro hydrolysis converts this compound to clindamycin, which has antibacterial activity. Clindamycin inhibits bacterial protein synthesis at the ribosomal level by binding to the 50S ribosomal subunit and affecting the process of peptide chain initiation and hence is active against the causative microorganism of acne vulgaris, that is, the anaerobic bacterium, Propionibacterium acnes.

The next most prescribed topical preparation was a salicylic acid face wash. Salicylic acid is the only beta-hydroxy acid used in skin care. It accomplishes the same goals in skin care as alpha-hydroxy acids such as lactic acid and glycolic acid, but it is used in a much weaker concentration. Salicylic acid is an exfoliant ingredient that is chemically similar to aspirin. Like aspirin, salicylic acid can remove redness and inflammation as it opens pores. This simple preparation was prescribed to almost 1/4th of the patients with different grades ranging from grade 1 to grade 4.

This was followed by the vitamin A analogue, Adapalene, which formed 13.24% of the total topically administered drugs.

Regarding the systemically prescribed drugs, azithromycin was the most commonly prescribed drug as it formed 1/3rd of the total drugs that were to be administered systemically, that is, orally. It is seen that Azithromycin was the most prescribed oral antibiotic in a similar Indian study carried out on the drug utilization pattern in the treatment of acne.[6] Azithromycin is a macrolide that has many advantages compared to other antibiotics. It is more stable than erythromycin in low gastric pH; it produces fewer gastrointestinal side-effects and presents no major drug interactions.[15] it also appears to be safer than the new tetracyclines such as lymecycline, in pediatric patients. Furthermore, the possible efficacy of a less frequent dosage improves compliance, cost-effectiveness and tolerability. This might explain its extensive use in treatment of acne. It's mechanism of action involves inhibition of bacterial protein synthesis, quorum-sensing and reduction the formation of biofilm.

Doxycycline follows Azithromycin, as it was the next most frequently prescribed systemic agent. Doxycycline inhibits bacterial protein synthesis by binding to the 30S ribosomal subunit and preventing access of aminoacyl tRNA to the acceptor (A) site on the mRNA-ribosome complex. Doxycycline has bacteriostatic activity against a broad range of Gram-positive and Gram-negative bacteria. 31 prescriptions of doxycycline in total were given out to the patients of acne of varying grades attending the dermatology outpatient department. Therefore, it formed 1/4th of the bulk of the systemic drugs prescribed.

It has been recommended that there is no justification for prescribing more than two drugs.[5] in our study, the average number of drugs per prescription was found to be 4.32, which is much more than the current recommendation. The increase in the number of drugs also increases the cost of prescription.

Quality of Life: A disease is not just characterized by its pathological manifestations, but also by its impact of the patients Quality of life. This crucial aspect, however, is very often overlooked by the physician while treating the patients. Measurement of quality of life is also necessary when assessing new therapies in audit for clinical services. Evaluation of the impact on quality of life, risk factors and preferences for the selection of treatment agents, may help to design more targeted interventions. Therefore, two robust questionnaires, the Dermatology Life quality Index (DLQI) and the Cardiff Acne Disability Index (CADI) were applied to measure the psychosocial impact of acne on the life of 90 consenting patients attending the dermatology outpatient department at a tertiary care teaching hospital.

The DLQI questionnaire[11] was designed by Finlay and Khan in 1992, and since then, it has vastly been used in different communities. The Dermatology Life Quality Index is a simple 10-question validated questionnaire that examines the effect of the skin problem on the patient's social and work life in the past one week. The questionnaire is available in three vernacular languages; Hindi, Gujarati & English. It is self-explanatory and can be handed to the patient for filling. The DLQI questionnaire is designed for use in adults.

The mean DLQI score in our study is 9.32 ± 6.479. According to the guidelines provided for the assessment of the DLQI, this score indicates that acne vulgaris does in fact have an effect on the life of patients, though it is moderate. This result is different from that obtained in a similar study carried out in Sarawak, Malaysia, where the mean DLQI score was 4.1 ± 4.51.[8] this shows that the Indian population is affected more than the Malaysian population by this skin condition. Looking into the individual domains of DLQI the domain which was impaired more in comparison was the symptoms and feelings domain which was dealing with questions related to symptoms of acne or embarrassment due to the disease. QOL also showed impairment in the social domain which had questions pertaining to social and leisure activities. The domains concerned with daily activities, personal relationships and treatment did not have a major impact on QOL.

From the survey, it was observed that the highest score was 26 obtained from patients of the age group 18 to 20 years.

The lowest score was 0 which translates as no impact of acne on the quality of life. This score was noted in the patients, also belonging to the age group of 18 to 20 years.

The Cardiff Acne Disability Index[10] consists of 5 questions that assess the patient's attitude towards the condition. Each question consists of four options and each question is graded with a maximum score of 3 and a minimum of 0. The CADI score is calculated by summing the score of each question resulting in a possible maximum of 15 and a minimum of 0. The higher the score, the more the quality of life is impaired.

The mean CADI score was 6.34 ± 3.625. This score is lower as compared to that obtained in an Indian study where in more than half (68.94%) the patients with varying degrees of acne scored 8 or more.

It was noted that the highest score obtained during the survey using CADI was 21 and was scored by the patients of the age group 21 to 23 years.

The lowest score was 0, indicating that acne vulgaris had no impact on the quality of life. This score belonged to the age group of 18 to 20 years.

Again in the CADI, questions related to patients' participation in the daily social events, relationship especially with the opposite sex, were answered in a way reflecting poor QOL.

The participants were concerned regarding feelings about their appearance as pointed out in the CADI score, the scores of the CADI also corresponded to the fact the patients were aggressive, frustrated , embarrassed about the disease.

The two QOL scales showed moderate correlation with the value of 0.67 at the level of significance was p is less than 0.0001. (p=0.000026)

This study holds value because it does not only analyzed the drug utilization pattern in the treatment of acne, but also assessed the psycho-social impact of the skin disease using two robust Quality of Life (QoL) questionnaires, that is, the Dermatology Life Quality Index (DLQI) and the Cardiff Acne Disability index (CADI).

However, this study did have its own limitations as the study has limited sample size of 90 patients. Hence, entire spectrum of the disease and QOL correlation will not be robust. As it was a prospective, single point study, of limited duration, the improvement in the quality of life of the patients suffering from different grades of acne vulgaris, could not be assessed.

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