DRUG UTILIZATION EVALUATION AND PRESCRIPTION ANALYSIS ACNE VULGARIS IN A DERMATOLOGIC DEPARTMENT: A CONCURRENT OBSERVATIONAL STUDY

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ABSTRACT

Background: Skin constitutes the largest organ of the human body accounting for about 15% of the body. Healthy and attractive skin plays an important role in people's self-esteem. Acne vulgaris is the most common chronic inflammatory skin condition which lasts for many years. Treatment and compliance with regimen are essential elements in overall effectiveness of therapy. Since oral and topical agents are important for treatment of acne vulgaris, periodic auditing of prescription is necessary to increase the therapeutic benefit and improve compliance. **Aims and objectives:** To assess drug usage of Acne vulgaris as a tool for ensuring rational drug therapy by using WHO core prescribing indicators. **Methodology:** A concurrent observational study was performed on patients of either gender treated for Acne Vulgaris at out-patients visiting dermatology department of Dr Sohana's Skin and Laser Clinic, Nadiad after the approval of ethics committee. Drug utilization evaluation was performed using WHO core prescribing indicators. **Results:** 152 patients were involved in this study. The drug utilization study showed that female patients (63%) visiting the dermatologic clinic were more as compared to male patients. Most of the patients were in the age group of 21 to 30 years which constitute about 57.89%. Amongst all the Grades of Acne Vulgaris, Grade 2 Acne was found in highest proportion (51%). Most of Anti- acne agents were prescribed by topical route (77%.) as compared to oral route (23%). 343(53.93%) drugs were prescribed in the form of lotion/ creams/ gels. Total of 152 patients diagnosed with Acne Vulgaris received 636 drugs out of which there were 90 supportive drugs. Commonly prescribed anti-acne agent by topical route was Clindamycin phosphate in

combination with Nicotinamide (13.99%) and 20.13% as a FDCs.198 (31.13%) drugs were prescribed as Monotherapy and 438 drugs (68.68%) as FDCs for Acne Vulgaris. 34.43% of Benzoyl Peroxide was mostly prescribed as Monotherapy for Acne Vulgaris. Commonly prescribed drug in patients with Grade 2 Acne Vulgaris is Clindamycin Phosphate and Nicotinamide numbered 48. **Conclusion:** It was concluded from the study that average number of drugs per encounter exceeds the optimal value of WHO Standards which indicates practice of polypharmacy. The prescribing pattern must be improved by prescribing drugs by generic name, by reducing the number of drugs per prescription, prescribing a smaller number of antibiotics to reduce bacterial resistance for Acne Vulgaris and prescribing the drugs from National Essential Drug List to encourage evidence-based prescribing.

KEYWORDS: Acne Vulgaris, Drug Utilization Review, Prescription, Dermatology.

INTRODUCTION

Skin constitutes the largest organ of the human body accounting for about 15% of the body. Healthy and attractive skin plays an important role in people's self-esteem.[1] Acne vulgaris is most common inflammatory disease of pilosebaceous unit resulting from androgen induced increased sebum production, abnormal keratinocyte multiplication and desquamation that leads to ductal obstruction, inflammation, and bacterial colonization of hair follicles on face, neck, chest, and back by *Propionibacterium acnes.*[2,3] Acne can appear as a spectrum of lesions, including non-inflammatory open (blackheads) and closed (whiteheads) comedones, inflammatory papules, pustules, nodules, and cysts. According to symptoms, acne can be classified as Grade 1, Grade 2, Grade 3, and Grade 4.[4]

Four processes play an important role in development of Acne
- Inflammatory mediators are released into the skin.
- Alteration of process called keratinisation that leads in formation of comedones.
- Increased androgen released leading to increased and altered sebum production.
- Follicular colonization of *Propionibacterium acnes*.

The exact sequence of events and how they interact remains unclear.[2]

Acne can be diagnosed by physical examination and clinical evaluation. Information like family history, signs and symptoms that are suggestive of hyperandrogenism, or other endocrine disorder, medications used by patients that can be associated with acne or use of external androgen should be taken from the patients.[5]

Before designing a treatment, it is most important to review patient's skin care routine which includes frequency of washing and use of cleansers and moisturizers. Patients with acne should limit washing twice daily, use gentle cleansers and avoid scrubs and other irritating products. Patients with sensitive skin should use fragrance free moisturizer, applied over topical medication so that it can minimize irritation. It may take 8 to 12 weeks for clinical improvement to occur. Sunscreen should be used in patients with post-inflammatory hyperpigmentation to prevent further darkening.

Various oral and topical agents are used for the treatment of acne.[6]

Topical Agents like

Topical treatment is enough for comedonal acne. For severe acne, topical treatment can be combined with systemic treatment.

1. Benzoyl peroxide (2.5-10% once daily).
2. Salicylic acid (0.05-2% once to thrice daily).
3. Tazarotene (0.05% once daily [HS]).
4. Tretinoin (0.1-0.25% once daily).
5. Adapalene (0.1% daily).
6. Erythromycin (2% & 4%) with zinc acetate (1.2% twice daily).
7. Clindamycin (1% twice daily).
8. Azelaic acid (20% twice daily).

Oral agents like

1. Erythromycin (250-500 mg twice daily).
2. Isotretinoin (0.5-1 mg/kg/day for 15-20 weeks).
3. Oral contraceptives.
4. Tetracycline (250-500 mg twice daily).
5. Doxycycline (50-100 mg twice daily).
6. Minocycline (50-100 mg twice).
7. Erythromycin (250-500 mg twice daily).

The reason for conducting DUE for anti-acne drugs is that it is most common chronic inflammatory skin condition which lasts for many years. Treatment and Compliance with regimen are essential elements in overall effectiveness of therapy.[7] Since oral and topical

agents are important for treatment of acne vulgaris, periodic auditing of prescription is necessary to increase the therapeutic benefit and improve compliance.[8]

This study was undertaken to determine the prescription patterns of drugs used to treat Acne Vulgaris.

MATERIALS AND METHODS

This was a concurrent Observational study conducted at Dr. Sohana's Skin and Laser Clinic, Nadiad, Gujarat from October 2022 to April 2023. Total 152 patients were selected randomly attending OPD of Acne Vulgaris, after fulfilling defined eligibility criteria.

Inclusion Criteria

- Patients of age: ≥12 to ≤ 30 years
- Patient of either gender (males, pregnant, non-pregnant and lactating women).
- Patient who willingly gives their concern.

EXCLUSION CRITERIA

- Patients of age > 30 years
- Patients with protozoal and viral skin infection.

The study protocol was submitted, and permission was obtained from Institutional Ethics Committee – Charusat before commencement of the study. For studying drug utilization pattern the following data was collected: 1) Age 2) Gender 3) Route of administration 4) History notes 5) Treatment charts 6) Distribution of patient with occupation. WHO prescribing core indicators was used in the study to determine rationality of prescriptions. These includes a) Average number of drugs per encounter b) Percentage of drugs prescribed by generic name c) Percentage of encounter with an antibiotic prescribed d) Percentage of drugs prescribed from essential drug list. All this information was collected in self-designed Case report form. After data collection, case data was entered in Microsoft Excel sheet and

The collected data was analyzed by using WHO Core prescribing indicators to determine the drug use and rationality of prescription.

a) Average number of drugs per encounter
- **Purpose:** To measure the degree of polypharmacy

- **Calculation:** Average = Total number of different drug product prescribed/Number of encounters surveyed

b) Percentage of drugs prescribed by generic name

- **Purpose:** To measure the tendency to prescribe by generic name
- **Calculation:** Percentage = Total number of drugs prescribed by generic name/Total number of drugs prescribed × 100.

c) Percentage of encounters with an antibiotic prescribed

- **Calculation:** Percentage = Total number of patients receiving antibiotics/Number of encounters × 100

d) Percentage of drugs prescribed from essential drug list or formulary

- **Purpose:** To measure the degree to which practices conform to a traditional drug policy, as indicated by prescribing from the national essential drugs list or formulary for the type of facility surveyed.
- **Calculation:** Percentage = Number of products prescribed which are listed on the essential drug list or formulary/Total number of products prescribed × 100.

RESULTS

152 patients were enrolled in this study.

Table 1: Demographic data according to age.

Age group (yrs.)	Number of patients	Percentage (%)
1-10	0	0
11-20	64	42.10
21-30	88	57.89
Total	152	100

The age of patients included in this study were from 12 to 30 years, with mean age of 76 ± 12 (mean ± standard deviation). According to age group the patients were divided into the group as 1 to 10 (n=0), 11 to 20 (n= 64) and 21 to 30 (n=88) as shown in above table.

Table 2: Gender wise categorization of Acne Vulgaris.

Gender	Number of patients (n)	Percentage
Male	56	37%
Female	96	63%
Total (N)	152	100%

The study shows that the percentage of female patients visiting dermatologist clinic for Acne Vulgaris were more as compared to male patients. The demographic data shows that out of 152 patients, 96 (63%) were females and 56 (37) were males.

Table 3: *Route of administration of anti- acne agents.*

Route of administration	Total number of drugs (n)	Percentage
Oral	144	23%
Topical	492	77%
Total (N)	636	100%

492 (77%) drugs were prescribed by topical route followed by 144 (23%) oral preparation.

Table 4: Types of dosage form of anti-acne agents prescribed.

Dosage Forms	Number of drugs (n)	Percentage
Lotion/creams/gels	343	53.93%
Tablets	144	22.64%
Face wash	82	12.89%
Shampoo	67	10.53%
Total Drugs (N)	636	100%

Commonly prescribed dosage forms were in form of lotion/creams/gels numbered 343 (53.93%), followed by 144 (22.64%) tablets/capsules, 82 (12.89%) facewashes and 67 (10.53%) shampoos.

Table 5: Distribution of disease as per grades of Acne Vulgaris.

Grade of Acne	Number of patients (n)	Percentage
Grade 1	38	25%
Grade 2	77	51%
Grade 3	28	18%
Grade 4	9	6%
Total (N)	152	100%

Most patients visiting the dermatologist clinic showed the symptoms of Grade 2 Acne. Out of 152 patients, 77 (51%) patients showed the symptoms of Grade 2 Acne, followed by Grade 1 Acne-38 (25%), and Grade 3 Acne-28 (18%) and lastly Grade 4 Acne-9 (6%) as showed in above table.

Table 6: *Anti- acne agents prescribed.*

Anti-acne drugs	Grade 1	Grade 2	Grade 3	Grade 4
Acmed plus foaming face wash	16	40	15	5
Sonise face wash	1	4	1	0

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Adapalene + clindamycin	20	31	4	2
Azithromycin	3	7	1	1
Benzoyl peroxide	10	36	18	4
Cholecalciferol	10	25	7	2
Ciclopirox and Zinc Pyrithione	2	1	1	1
Clindamycin phosphate	2	2	0	0
Clindamycin Phosphate and Nicotinamide	11	48	24	6
Glycolic acid	4	5	0	1
Doxycycline and Lactic acid bacillus	5	18	5	0
Isotretinoin	1	9	20	9
Ketoconazole	2	4	1	1
Ketoconazole and Zinc Pyrithione	14	27	10	3
Nadifloxacain	2	2	0	1
Salicylic acid and nicotinamide	0	2	0	0
Sulfamethoxazole and Trimethoprim	0	1	0	0
Zinc and Niacinamide	12	20	4	2
Supportive treatment	26	45	14	5
Total drugs (N)	141	327	125	43

There was total 636 drugs prescribed in 152 patients. Supportive treatment for Acne Vulgaris was commonly prescribed. Supportive treatment includes moisturizers, sun blocking agents whitening cream and tablets, vitamins and minerals supplement and anti-allergic drugs. Commonly prescribed drug for Acne Vulgaris was topical Clindamycin phosphate and Nicotinamide-89 (13.99%). This was followed by facewash-Acmed plus foaming face wash-76 (11.94%). Other drugs used to treat acne vulgaris are in table above.

Table 7: Result of ANOVA with Tukey's Multiple Comparisons.

Repeated measures ANOVA summary		
Assume Sphericity?	No	
F	15.02	
P value	**0.0001**	
P value summary	***	
Statistically singnificant (P < 0.05)?	Yes	
Geisser - Grrenhouse 's epsilon	0.4949	
R squared	0.4548	
Data summary		
Number of treatments (columns)		4
Number of subjects (rows)		19
Number of missing values		0
Tukey's Multiple Comparison Test		
	Summary	**Adjusted P value**
Grade 1 vs. Grade 2	**	0.0039
Grade 1 vs. Grade 3	ns	0.9648
Grade 1 vs. Grade 4	*	0.0190
Grade 2 vs. Grade 3	**	0.0035

Grade 2 vs. Grade 4	**	0.0020
Grade 2 vs. Grade 4	*	0.0182
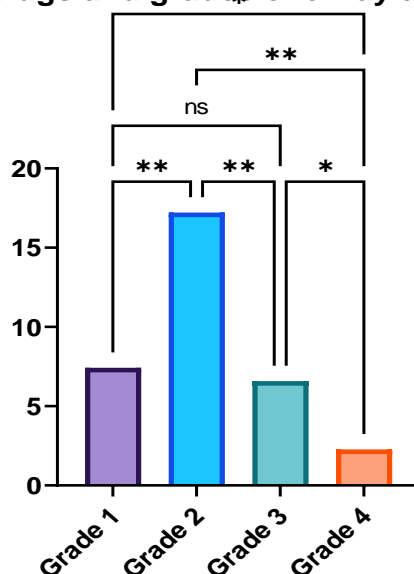
One-way ANOVA with Tukey's Multiple Comparisons Test was performed to identify the significant difference between the treatments given in different grade of Acne Vulgaris. The above table shows that there is no significant difference between treatment given for Grade 1 and Grade 3 of Acne Vulgaris. Rest all shows that there is a significant difference between the treatment given for different Grades of acne.

Table 8: Analysis of anti-acne agents using who core prescribing indicators.

WHO Core prescribing indicators	Results	Optimal Value
Average number of drugs per encounter	4.28	< 2
Percentage of drugs prescribed by generic name	0%	100%
Percentage of encounters with an antibiotic prescribed	82.23%	<30%
Percentage of encounters with an injection prescribed	0%	<20%
Percentage of drugs prescribed from NLEM	19.20%	100%

Total of 152 patients were diagnosed with acne vulgaris were prescribed with total 651 drugs. As per WHO core prescribing indicators, average number of drugs per encounter was 4.28 ± 1.51 that was not within the limit of WHO standards which indicates the practice of polypharmacy that leads to poor compliance and increase the cost of the therapy. Percentage of drugs prescribed by generic name was 0% which increases the risk of dispensing errors. The percentage of encounters with an antibiotic prescribed was found to be 82.23% which exceeds the limit of optimal value of WHO standard that increases the risk of bacterial resistance. Percentage of drugs prescribed from NLEM was 19.20% which is lesser than optimal value of WHO standards and that increases the chances of prescribing incorrect dosage form and strength, and least cost-effective drugs.

DISCUSSION

In this study age wise distribution was analysed, and it was found that most of the prescriptions were in age group of 21 to 30 years (57.89%) followed by 11 to 20 years (42.10%) which is like the study result concluded by **Nandini T et al. (2016)**[9] in which most of the prescriptions were in the age group of 21 to 40 years (48.09%).

The study shows that the percentage of female patients (63.15%) visiting dermatologist clinic for Acne Vulgaris were more as compared to male patients (36.84%). In a similar study conducted by **Sameer Dharrao et al. (2019)**[10] majority of patients were found to be female (54.59%).

Distribution of diseases as per grade of Acne vulgaris was analysed and most of the patients showed the symptoms of Grade 2 acne (50.65%) followed by Grade 1 (25%) and Grade 3 (18.42%). A similar study was conducted by **Sameer Dharrao et al. (2019)**[10] in which most patients were found with grade 2 acne (52.66%). Another study conducted by **Mahesh N. Belhekar, et al. (2022)**[11] concluded that most of the patients showed the symptoms of Grade 2 acne (41.5%). Furthermore, a similar study by **Naveen Kumar Kansai et al. (2021)**[12] relieved that Grade 2 acne was found to be 43.8%.

This study manifested that mostly drugs were prescribed by topical route (77.35%) compared to oral route (22.64%). A similar study was conducted by **Nandini T et al. (2016)**[9] which concluded that most of the drugs were prescribed by topical route (54.13%). Another study by **Nibedita Patro et al. (2015)**[13] and **Donepudi Pavan Kumar et al. (2019)**[14] showed that drugs were prescribed predominantly by topical route was 52.56% and 62.4% respectively. In

contrast, a study conducted by **Khalid A et al. (2016)**[15] reported that oral drugs were majorly prescribed (73.4%).

This study concluded that commonly prescribed dosage forms were in form of lotion/creams/gel numbered 343 (53.93%), followed by 144 (22.64%) tablets/capsules, 82 (12.8%) facewashes and 67 (10.53%) shampoos. On contrary, a study conducted by **Amit Gupta et al. (2017)**[7] concluded that most prescribed formulation was gel (32%), followed by tablets (27%), creams (18%), capsules (8%), lotions (5%0, shampoos (4%), facewash (3%), acne soaps (2%) and ointments (1%). In this study there was total 636 drugs prescribed in 152 patients. Out of which Supportive treatment for Acne Vulgaris was 14.15%. Topical Clindamycin phosphate in combination with Nicotinamide (13.99%) was commonly prescribed drug for Acne Vulgaris followed by Acmed Plus Foaming face wash (11.94%). Oral Cholecalciferol (6.91%) was mostly prescribed drug for Acne Vulgaris followed by Isotretinoin (6.13%). These findings were different with the studies conducted by **Pooja M et al. (2017)**[8]**, Vishal P. Giri, et al. (2014)**[16]**, Vinay Sharma et al. (2016)**[17] **and Sameer Dharrao et al. (2019)**[10] which showed that topical Benzoyl peroxide was commonly prescribed. A study conducted by **Nibedita Patro et al. (2015)**[13] revealed that Oral Isotretinoin was mostly prescribed in oral formulation whereas study conducted by **Sameer Dharrao et al. (2019)**[10] revealed that Azithromycin followed by Doxycycline was commonly prescribed oral drug.

This study showed 198 (31.13%) drugs were prescribed as a monotherapy and 438 (68.86%) drugs were prescribed as FDCs. Benzoyl peroxide (34.34%) was commonly prescribed monotherapy for Acne patients which were accompanied by cholecalciferol.

(22.23%), Isotretinoin (19.69%), Azithromycin (6.06%), Glycolic acid (5.05%), Ketoconazole (4.04%), supportive treatment (4.04%) (which includes Vitamins supplement, whitening lotion, and anti-allergic drugs), Nadifloxacin (2.52%), and clindamycin phosphate (2.02%). Clindamycin phosphate and nicotinamide (20.31%) was commonly prescribed FDC followed by supportive treatments (18.72%) (which includes moisturizers, sun blocking agents, whitening cream and lotions and vitamins and mineral supplements), Acmed Plus Foaming face wash (17.35%), Adapalene and clindamycin (13.01%), ketoconazole and zinc Pyrithione (12.32%), Doxycycline and lactic acid bacillus (6.39%), Sonise face wash (1.36%), ciclopirox and zinc Pyrithione (1.14%), Salicylic acid and nicotinamide (0.45%) and sulfamethoxazole and trimethoprim (0.22%). These findings contradict the study conducted

by **Sameer Dharrao et al. (2019)[10]** which concluded that monotherapy was prescribed in 35.26% of cases. A study conducted by **Amit Gupta et al. (2017)[7]** showed that FDCs were prescribed in 31% of cases which is different from this study.

This study analysed grade wise distribution of anti-acne drugs which concluded that Grade 2 Acne was found in greater proportion in which mostly prescribed drug was clindamycin phosphate and nicotinamide (n=48) followed by Supportive treatment (n=45), Acmed Plus foaming face wash (n=40) and Benzoyl Peroxide (n=36). A study conducted by **Amit Gupta et al. (2017)[7]** showed that 84% of patients were diagnosed with grade II acne and Grade II acne patients were treated with antihistamines, anti-inflammatory drugs, and vitamin supplements by oral route. Topical therapy includes steroids alone or in combination with antifungal drug in form of facewash, shampoo, etc for grade II acne.

Total of 152 patients diagnosed with acne vulgaris were prescribed with total 651 drugs.

A. Average number of drugs per encounter

Based on WHO core prescribing indicators the average number of drugs per encounter was found to be 4.28±1.51. which is comparable with the study conducted by **Amit Gupta et al. (2017)[7]** where average number of drugs per prescription was found to be 4.14. This finding is different from the study conducted by **Sameer Dharrao et al. (2019)[10]** where average number of drugs per encounter were 2.29.

B. Percentage of drug prescribed by generic name

The percentage of drug prescribed by generic name was found to be 0 % which is comparable with the study conducted by **Sameer Dharrao et al. (2019)[10]** where percentage of drugs prescribed by brand names are 100%.

C. Percentage of an encounter with an antibiotic prescribed

Percentage of an encounter with an antibiotic prescribed was found to be 82.23% which is different from the study conducted by **Sameer Dharrao et al. (2019)[10]** where percentage of prescriptions with antibiotic prescribed were 64.73%.

D. Percentage of drug prescribed from NLEM

Percentage of drug prescribed from NLEM was found to be 19.20%. This similars with the study conducted **Sameer Dharrao et al. (2019)[10]** by where Percentage of drug prescribed from NLEM was found to 76%.

CONCLUSION

This study was conducted in middle Gujarat concluded that prescribing pattern of Anti-Acne drugs was irrational. By using WHO core prescribing indicators it was revealed that average number of drugs per prescription was found to be higher. Thus, prescriber must consider the factor of polypharmacy. Antibiotics prescribed were in larger amount. It was observed that drugs were not prescribed by generic name. Furthermore, drugs to treat acne were not prescribed from NLEM.

Thus, to promote rational use of drugs and to encourage evidence-based prescribing, practice of polypharmacy must be reduced, drugs must be prescribed from NLEM and by generic name.

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