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Original Research Article

An observational study to assess the drug prescription pattern and quality of life of acne vulgaris patients in a tertiary care center in India

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ABSTRACT

Background: The study was conducted to assess the prescription pattern of acne vulgaris patients, and impact of anti-acne treatment on severity of acne and change in quality of life (QoL) in patients.

Methods: A prospective observational study was conducted in dermatology OPD of a tertiary care hospital with 160 patients of acne vulgaris. All patients with acne vulgaris >18 years, of either sex were included while those with pre-existing other cutaneous or systemic diseases, pregnant and lactating females and not giving consent were excluded from the study. Prescriptions were analysed and patients were followed-up at 2 and 6 weeks for assessment of change in acne severity and QoL, determined by GAGS score and CADI difference score, respectively.

Results: Mean age of patients was 20.7±2.5 years, with males and females constituting 62 (38.8%) and 98 (61.3%) patients, respectively. Acne was mild in 88 (55%), moderate in 51 (31.9%) and severe in 21 (13.1%) patients. A total of 537 drugs were prescribed to all patients, with an average of 3.36 drugs per prescription. Two, 3 and 4 drugs were prescribed in 2.5%, 59.4% and 38.1% patients, respectively. There was significant improvement in the GAGS score ($p<0.001$) and QoL (CADI score difference) ($p<0.001$) at 2 and 6 weeks follow-up compared to initial visit.

Conclusions: Polypharmacy was a common practice in anti-acne treatment. However, it was associated with improvement in acne severity and QoL.

Keywords: Anti-acne treatment, CADI, GAGS, Poly-pharmacy

INTRODUCTION

Acne vulgaris is a major cosmetic concern in adolescents and adults. The treatment include several options- 1) topical/oral retinoids, having comedo-mimetic and sebo-suppressive and anti-inflammatory properties, 2) topical/oral antibiotics, having anti-microbial action, 3) Benzoyl peroxide, having anti-inflammatory and comedolytic action, 4) hormonal agents, causing sebo-suppression. The American Academy of Dermatology (AAD 2016) have given treatment algorithms depending on the severity of acne vulgaris. Thus, the treatment approaches may be different in patients.¹

Studies of drug use patterns, in a particular disease condition in a hospital setting, assists in analysing the rational use of drugs.^{2,3} Intermittent and regular audits are essential as they help to assess therapeutic efficacy, reduce occurrence of adverse effects and most importantly, provides feedback to prescribers to check, and monitor if the prescribing practices are in accordance with the standards of medical treatment as per the guidelines.^{3,4} This study was planned to assess the demographic pattern and drug utilization of acne vulgaris patients, and the impact of anti-acne medications on the severity of acne and quality of life (QoL).

METHODS

This cross-sectional study was conducted in a Dermatology out-patient department settings of a tertiary care hospital in Navi Mumbai, India from April 2017 to March 2018.

Inclusion criteria

Patients, more than 18 years of either sex, with acne vulgaris seeking medical intervention for acne were included in the study following a written informed consent.

Exclusion criteria

Patients with co-existing other cutaneous or systemic diseases, pregnant and lactating females and not consenting for participation were excluded.

Permission of the Institutional Ethics Committee was obtained before commencement of the study (2017/03/SC/32). The demographic details, clinical history, examination findings, and drugs prescribed were recorded with the help of predesigned case record form. Severity of acne was judged according to the Global Acne Grading System (GAGS).⁵ QoL was assessed using a licensed version of Cardiff Acne Disability Index (CADI).⁶ The Hindi version of the questionnaire, which has been validated earlier, was used for patients who were not comfortable for CADI in English.⁷ Patients were followed up at 2 and 6 weeks of initial visit for assessing the change in severity and QoL. Subjective assessment of acne improvement was evaluated using visual analogue scale (VAS) at follow-up, wherein 0 and 10 indicated no improvement and complete improvement, respectively.

Data from the case record forms was entered in a Microsoft excel sheet and analysed using SPSS version 21 software. Descriptive statistics were assessed and represented as Mean±SD, frequencies and percentages. Quantitative data (which was not normally distributed) within the group at more than 2 intervals was compared using Friedman's test, with post hoc analysis using Wilcoxon signed rank test. The level of significance in the study was <0.05.

RESULTS

During the study period, 160 patients consented for participation. Demographics and other characteristics of the patients have been described in Table 1.

Previous treatment for acne was taken by 35 (21.9%), of which 9 (5.6%) had taken oral medications while 26 (16.3%) had taken topical treatment. Among these, 25 (71.4%) reported cure for acne. Among the patients, severity of acne was mild in 88 (55%), moderate in 51 (31.9%), and severe in 21 (13.1%).

Table 1: Demographic characteristics of all participants included in the study.

Demographics	Values	
Age (in years)	20.6±2.5	
Gender	Males	62 (38.8%)
	Females	98 (61.3%)
Total duration of history of acne	<2 months	17 (10.6%)
	3-6 months	23 (14.4%)
	6-12 months	34 (21.3%)
	>12 months	86 (53.8%)
Duration of current acne complaints	<2 months	21 (13.1%)
	3-6 months	37 (23.1%)
	6-12 months	70 (43.8%)
	>12 months	32 (20%)
Aggravating factors*	Stress	85 (53.2%)
	Seasonal variation	55 (34.4%)
	Use of cosmetics	10 (6.3%)
Associated symptoms*	Seborrhoea	54 (33.8%)
	Weight gain	1 (0.6%)
Personal habits	Smoking	8 (5%)
	Alcohol consumption	0 (0%)
Diet	Vegetarian	61 (38.1%)
	Non-vegetarian	99 (61.9%)
Menstrual history (in females)	Irregular	1 (1%)
	Regular	97 (99%)
Age of menarche (in females)	12 years	22 (22.4%)
	13 years	47 (48%)
	14 years	28 (28.6%)
	15 years	1 (1%)
Frequency of menstrual cycle (in females)	28-30 days	91 (92.9%)
	>45 days	7 (7.1%)
Duration of menstruation (in females)	3-5 days	45 (45.9%)
	5 days	38 (38.8%)
	>5 days	15 (15.3%)

*values are mutually exclusive of each other

Prescription pattern analysis

Numbers of drugs prescribed, anti-acne drugs were 2 in 4 (2.5%), 3 in 95 (59.4%), and 4 in 61 (38.1%), with an average of 3.36 drugs per prescription.

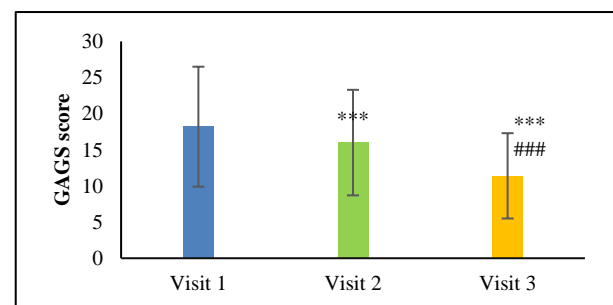


Figure 1: Change in severity of acne as assessed by GAGS.

Friedman's test, ***p<0.001 versus visit 1, ###p<0.001 versus visit 2.

Medications prescribed according to their severity of acne have been described in Table 2, 3 and 4. Additionally, chemical peels were performed in 8 (5%) patients. Drugs prescribed to the patients were in according with the AAD 2016 guidelines.

The severity of acne, as assessed by GAGS score, improved significantly ($p < 0.001$) from 18.2 ± 8.3 at 1st visit, to 16 ± 7.3 and 11.4 ± 5.9 at 2 and 6 weeks, respectively (Figure 1).

Table 2: Outline of medications prescribed to patients with mild acne in the study.

Generic Name	Brand name	Dose	Drug route	Frequency of administration	Duration (in weeks)	Number of patients*	% (of 88)*
Adapalene+ Clindamycin	Deriva CMS gel	0.1% w/w + 1% w/w	Topical	OD	6	68	77.3
Adapalene+ Benzoyl peroxide	Minoz BPO gel	0.1% w/w + 2.5% w/w	Topical	OD	6	22	25
Clindamycin	Clindac A gel	1% w/w	Topical	OD	6	5	5.7
Clindamycin+ Nicotinamide	Glocin gel	1% w/w + 4% w/w	Topical	OD	6	54	61.4
Doxycycline	Doxy	100 mg	Oral	OD	6	30	34.1
Foaming facewash	Kimklin aha facewash	-	Topical		-	1	1.1
Salicylic acid+ Glycolic acid	Clindac A facewash	-	Topical	BD OD	6	79 2	92

*values are mutually exclusive of each other.

Table 3: Outline of medications prescribed to patients with moderate acne in the study.

Generic Name	Brand Name	Dose	Drug route	Frequency of administration	Duration (in weeks)	Number of patients*	% (of 51)*
Adapalene+ Clindamycin	Deriva CMS gel	0.1% w/w + 1% w/w	Topical	OD	6	51	100
Azithromycin	Azee	500 mg	Oral	OD	6	7	13.7
Clindamycin	Clindac A gel	1% w/w	Topical	OD	6	30	58.8
Clindamycin+ Nicotinamide	Glocin gel	1% w/w + 4% w/w	Topical	OD	6	19	37.2
Doxycycline	Doxy	100 mg	Oral	OD	6	32	62.7
Doxycycline+ Lactobacillus	Doxy-bond LB	100 mg	Oral	OD	6	11	21.6
Foaming facewash	Kimklin aha facewash	-	Topical		-	32	62.7
Salicylic acid+ Glycolic acid	Clindac A facewash	-	Topical	OD BD	6	3 9	23.5

*values are mutually exclusive of each other.

Table 4 Outline of medications prescribed to patients with severe acne in the study.

Generic Name	Brand Name	Dose	Drug route	Frequency of administration	Duration (in weeks)	Number of patients *	% (of 21)*
Adapalene+ Clindamycin	Deriva CMS gel	0.1% w/w + 1% w/w	Topical	OD	6	19	90.5
Adapalene+ Benzoyl peroxide	Minoz BPO gel	0.1% w/w + 2.5% w/w	Topical	OD	6	2	9.5
Clindamycin	Clindac A gel	1% w/w	Topical	OD BD	6	18 1	90.5
Clindamycin+ Nicotinamide	Glocin gel	1% w/w + 4% w/w	Topical	OD	6	1	4.8
Doxycycline	Doxy	100 mg	Oral	OD	6	2	9.5
Isotretinoin	Isotret	20 mg	Oral	OD	60 days	19	90.5

Continued.

Generic Name	Brand Name	Dose	Drug route	Frequency of administration	Duration (in weeks)	Number of patients *	% (of 21)*
Foaming facewash	Kimklin aha facewash	-	Topical		-	19	90.5
Salicylic acid+ Glycolic acid	Clindac A facewash	-	Topical	OD	6	1	4.8

*values are mutually exclusive of each other.

The VAS scores at 2 and 6 weeks were 5.9 ± 1.3 and 7.4 ± 1.2 , respectively, indicating improvement in acne with treatment, as perceived by the patients.

The quality of life improved significantly ($p < 0.001$), with improvement in CADI difference scores from 5.1 ± 3.2 at 1st visit to 4.5 ± 2.9 and 2.9 ± 2.6 , at 2 and 6 weeks, respectively (Figure 2).

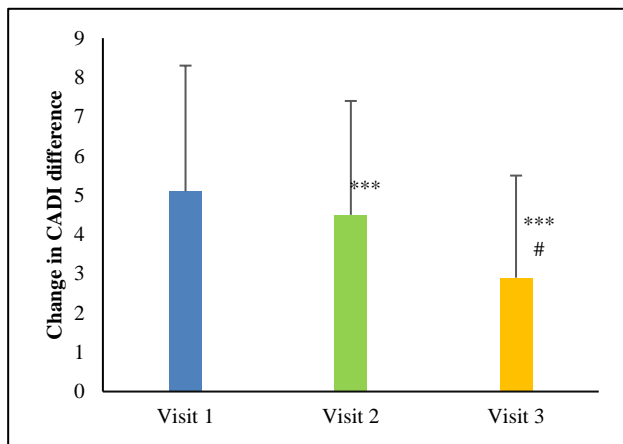


Figure 2: Improvement in quality of life as assessed by change in CADI.

Friedman's test, *** $p < 0.001$ versus visit 1, # $p < 0.05$ versus visit 2.

DISCUSSION

Prescription pattern is an important tool in determining the quality of patient care in a particular health care setting. Drug utilization studies assist to objectively evaluate the practices of health professionals and give them feedback regarding the same, in order to stimulate them to think over their practices. This helps to determine and encourage rational use of drugs in particular patient population. This study was carried out in an OPD setting in dermatology in a tertiary care hospital.

In present study, about 59.4% patients of acne vulgaris in the study had 3 drugs, with an average of 3.36 drugs per prescription. According to severity, among patients with mild acne, 77.3% received adapalene + clindamycin gel, 61.4% received clindamycin + nicotinamide gel, and 92% received salicylic acid + glycolic acid facewash. Among patients with moderate acne, 100% received adapalene + clindamycin gel, 62.7% received oral doxycycline and foaming facewash, and 58.8% received clindamycin gel. Among patients with severe acne, 90.5% received

adapalene + clindamycin gel, clindamycin gel, foaming facewash, and oral tablet of isotretinoin.

Different studies have reported different proportion of patients with varied severity of acne. In present study, acne was graded according to the Global Acne Grading System (GAGS).⁵ More than half (55%) patients had mild acne, 31.9% had moderate acne, while 13.1% had severe acne. In this study, GAGS was used for classifying acne as it is a validated scale and most importantly, quantifies the measure of acne severity making it more objective in use. Most of the previous similar studies, have used acne grading suggested by Tutakne et al.⁵ The authors agree that though the scale proposed by Tutakne et al is a simple grading system, it is a subjective scale depending on the assessor and does not take into consideration the lesions present all over the body. Moreover, its use may be confusing when mixed lesions are present. Various studies have segregated the severity of acne as grade 1, 2, 3 and 4.⁸⁻¹²

In present study, 3.36 drugs per prescription were noted. The average number of medications per prescriptions by various studies are as follows- Kumar et al- 4.76, Patro et al- 3.003, Agarwal et al- 4.01 drugs, Kamerkar- 3.04, Nandini et al- 2.49, Gupta et al- 4.14, Chandani et al- 4.32 drugs, Pooja et al- 1.77 drugs.⁸⁻¹⁵ Thus, from all studies, it can be observed that multidrug therapy is a common practice in acne vulgaris patients.

In current study, all drugs to the acne vulgaris were prescribed by brand names. Similarly, use of brand names was reported as 100% by Kumar et al, 48% by Agarwal et al, 98.7% by Pooja et al study.¹²⁻¹⁴ In present study, monotherapy was not observed, with 2 drugs prescribed in 2.5%, 3 drugs prescribed in 59.4%, and 4 drugs prescribed in 38.1%. Topical medications constituted 81.19% of all medications prescribed while 18.8% were oral medications. Thus, overall multidrug therapy and predominantly topical medications was a common practice in the current Institutional settings. Apart from drugs for acne vulgaris, no additional/concomitant medications were prescribed in the treatment. In Giri et al study, topical monotherapy was prescribed in 80% while topical polytherapy was prescribed in 20% patients, and systemic monotherapy was prescribed in 42.5% and polytherapy in 57.5%.¹⁶ In Kumar et al study, of all the total medicines (n=1135), topical therapy was constituted 58.5% while oral therapy constituted 41.5% of all medicines. Among the topical drugs, 96.38% were single while 3.08% were combination medications, while among the oral drugs, 97.66% were single while 2.34% were

combinations.¹³ In Patro et al study, among the total drugs prescribed, oral drugs constituted 47.44%, while drugs given topical route constituted 52.26%, with practice of monotherapy in 6.2% and polytherapy in 93.8%.⁸ In Agarwal et al study, in 1164 prescriptions, among oral drugs, single drug was prescribed in 36%, two drugs in 53%, and three drugs in 10.6%, while among topical medications, single topical agent was used in 55%, two drugs were used in 45%, and three drugs were used in 0.5%.¹⁴ In Nandini et al study, 15.24% prescriptions had single drug, 48.09% had 2 drugs, 25.71% had 3 drugs and 10.95% had >4 drugs.⁹ In their study, 46.2% drugs were prescribed by oral route and 53.8% were by topical route. In Sharma et al study, topical monotherapy was prescribed in 81.76% patients, while topical polytherapy was practiced in 18.23%.¹⁷ In Gupta et al study, 33% drugs were prescribed by oral route while 67% drugs were prescribed by topical route.¹⁰ In Chandani et al study, 69.92% drugs were topical and 30.07% drugs were oral.¹¹ In Pooja et al study, 41% prescriptions had single drug, 42.2% had 2 drugs, 15.6% had 3 drugs and 1.2% had 4 drugs. In their study, 83.99% drugs were given for topical applications and 16.01% were given for use by systemic route.¹² Thus, in almost all studies, the topical route was the most common. This might be due to use of topical medications in all the severity of acne while systemic use is generally limited to the higher grade of acne severity.

In Giri et al study, among topical medications given as monotherapy, 2.5% and 5% benzoyl peroxide was prescribed in 18.3% and 26.7% patients, respectively, 15.8% with clindamycin 1%, 9.2% with adapalene 0.05%, and 5.8% with ketoconazole 10%. Topical polytherapy medications used in their study were clindamycin phosphate (1%), aloe vera (10%), liquid paraffin (7%), and white soft paraffin (5%) in 20% patients.¹⁶ In Kumar et al study, among the single topical preparations, clindamycin was most common used in 30.87% followed by nicotinamide in 24.85%, while among topical combinations, mometasone + miconazole was commonest in 86.36%.¹³ In Agarwal et al study, among the topical medications with monotherapy, clindamycin was most common in 28%, followed by benzoyl peroxide in 12% and tretinoin in 10%, while among those with polytherapy topical drugs, clindamycin + benzoyl peroxide was used in 25%, followed by clindamycin + tretinoin in 13%, with overall clindamycin being the most common topical agent.¹⁴ In Kamerkar study, among topical formulations, clindamycin was most common in 48.4% patients, followed by adapalene in 26.56%, and salicylic acid in 15.6%.¹⁵ In Nandini et al study, among the topical agents, clindamycin was commonest in 13.24%, followed by azithromycin in 11.87%, tretinoin in 11.42%, benzoyl peroxide in 4.95%, and adapalene in 4.64%.⁹ In Sharma et al study, among the topical monotherapy, benzoyl peroxide 5% was given 30%, adapalene 0.05% in 11.76%, clindamycin 1% in 15.29%, benzoyl peroxide 2.5% in 12.35%, and ketoconazole in 12.35%, while among those with topical polytherapy, clindamycin phosphate 1%, aloe vera 10%, liquid paraffin 7%, white

soft paraffin 5% was prescribed in 18.24%.¹⁷ In Gupta et al study, among topical agents, clindamycin was most common in 79.78%, followed by adapalene in 63.93%, tretinoin in 28.4%, ketoconazole in 11.5%, and mometasone in 7.65%.¹⁰ In Chandani et al study, out of the prescribed topical drugs, clindamycin phosphate was most commonly prescribed (26.83%), followed by salicylic acid facewash (24.26%), adapalene (13.24%), benzoyl peroxide (8.09%), isotretinoin (6.99%) and nicotinamide (6.62%).¹¹ In Pooja et al study, among the 514 drugs prescribed for topical use, benzoyl peroxide was most common in 19.46%, followed by tretinoin + clindamycin in 17.12%, facewash in 15.56%, tretinoin in 12.45%, clindamycin in 10.51%, and adapalene + benzoyl peroxide in 7.78%.¹²

In current study, among the drugs prescribed by oral route, doxycycline was most common (63.36%), followed by isotretinoin (18.81%), doxycycline + lactobacillus (10.89%), and azithromycin (6.93%). In Giri et al study, systemic drugs as monotherapy were prescribed, with azithromycin in 30% and levocetirizine in 12.5%, polytherapy comprising of doxycycline and ranitidine were prescribed in 57.5%.¹⁶ Among oral drugs in Kumar et al study, antibiotics constituted 43.31%, multivitamins were 27.81%, antifungals were prescribed in 14.64%, antihistaminics were 8.06% and miscellaneous drugs constituted 6.15%. Among antibiotics, azithromycin was most commonly prescribed (85.78%), among antifungals, fluconazole was common (63.76%), among antihistaminics, cetirizine was common (58.63%).¹³ Among oral drugs in Patro et al study, isotretinoin was commonly prescribed constituting 68.1% of all oral drugs, followed by 31.9% antibiotics, of which doxycycline was most common (54.18%), followed by azithromycin (38.73%), minocycline (5.45%), and clarithromycin (1.64%).⁸ In Agarwal et al study, among the oral drugs with monotherapy, vitamin A was most common in 20%, followed by azithromycin in 7%, doxycycline in 5% and vitamin C in 4%, while among those with polytherapy, vitamin A + azithromycin was used in 23%, vitamin A + vitamin C in 18%, vitamin A + vitamin C + azithromycin in 9% were common, with overall, vitamin being the most commonly prescribed oral medication and azithromycin being the most common antibiotic prescribed.¹⁴ In Kamerkar et al study, among the orally administered drugs, azithromycin was most common in 62.5% patients, followed by isotretinoin in 12.5%.¹⁵ In Nandini et al study, among oral medications, azithromycin was most common in 15.53%, followed by doxycycline in 11.42%, nadifloxacin 7.31%, and retinoids in 5.94%.⁹ In Sharma et al study, among those with systemic monotherapy, azithromycin 500 mg was prescribed in 28.82%, levocetirizine 5 mg in 13.53%, while among those with systemic polytherapy, doxycycline 100 mg and ranitidine 150 mg was prescribed in 57.65% patients.¹⁷ In Gupta et al study, among the oral drugs, azithromycin was most common in 41.53%, followed by doxycycline in 28.96%, isotretinoin in 15.3%, minocycline in 14.75%, and fluconazole in 15.57%.¹⁰ Among the systemically

administered drugs in Chandani et al study, azithromycin was most common (33.33%), followed by doxycycline (26.49%), and isotretinoin (20.51%).¹¹ In Pooja et al study, among the 98 drugs used by systemic route, doxycycline was most common in 55.1%, followed by azithromycin in 34.7%, isotretinoin in 6.12%, and erythromycin in 4.08%.¹²

Published literature revealed that majority of studies had described the prescription pattern of drugs altogether for acne patients, irrespective of the severity of the disease. The investigators in the current study are of the view that the treatment of the acne patients is guided according to the standard guidelines which state different mode of treatment approaches depending on the severity of the acne disease, and thus, severity of acne significantly affects the prescription of acne vulgaris patients. In the patients with mild acne, salicylic acid + glycolic acid facewash was most commonly prescribed in 92% patients, followed by adapalene + clindamycin in 77.3% followed and clindamycin + nicotinamide in 61.4%. In mild acne, among the oral drugs, only doxycycline was prescribed in 34.1%. Comparatively, in patients with moderate acne, adapalene + clindamycin was prescribed in all patients, followed by foaming facewash in 62.7%, and clindamycin in 58.8%. Among the oral medications, doxycycline was used in 62.7%, while combination of doxycycline + lactobacillus was used in 21.6%, contributing to a total of 84.3% patients of moderate acne being prescribed with doxycycline as an antibiotic. In severe acne patients, among topical medications, adapalene + clindamycin, clindamycin, and foaming face wash were used in 90.5% patients, while among oral medications; isotretinoin was given in 90.5% patients. Thus, a specific prescription pattern in a certain severity of acne disease indicating the most preferred treatment. International guidelines were followed in our study.

Acne vulgaris significantly affects the quality of life as demonstrated in multiple studies.¹⁸⁻²⁰ The mean CADI score decreased at subsequent visits indicating that the quality of life improved with treatment of acne. This was mostly affected by the improvement in severity of acne due to effect of anti-acne medications. Thus, though polypharmacy may be a common practice in anti-acne medications, the following of AAD guidelines in treatment of acne, benefit the patient in terms of therapeutic benefit and QoL.

CONCLUSION

Multidrug therapy is a common practice in acne vulgaris patients. Topical medications contribute to about 80% of anti-acne medications in practice. Anti-acne medications lead to improvement in severity of acne and quality of life in patients.

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Conflict of interest: None declared

Ethical approval: The study was approved by the Institutional Ethics Committee (2017/03/SC/32)

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