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Section A-Research paper

STUDY OF DRUG UTILIZATION PATTERN FOR ACNE VULGARIS IN THE DEPARTMENT OF DERMATOLOGY AT INTEGRAL INSTITUTE OF MEDICAL SCIENCES AND RESEARCH

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Abstract

Background: Acne vulgaris is common skin disorder encountered in skin outpatient department in day to day practice. Acne can cause psychological distress, low self-esteem, and social withdrawal, affecting quality of life as much as more physically disabling diseases such as asthma and diabetes. Drug used in dermatological problems especially in acne are one of the top selling drugs in India however they are least studied with respect to drug utilization. Present study was undertaken to analyze drug utilization in various prescriptions at OPD & IPD of Department of Dermatology of Integral Institute of Medical Sciences and Research.

Methods: A prospective, cross-sectional, non-experimental (observational) study was performed in IPD & OPD of dermatology department of Integral Institute of Medical Sciences and Research over a period of 6 months. During the study a total of 100 prescriptions were analyzed. The patient demographic details like name, age, sex, place, and weight were noted in specially designed patient documentation form. Diagnosis, patient complaints, number of drug prescribed, social history, generic name, brand name, were recorded daily in patient data collection form. From the prescriptions the drug interactions were identified by using drug interaction checker and micromedex software.

Results: Among 100 patients it was observed that maximum no of ptients were females (58%). Highset no of patients were from age group 21-25 years of age. Grade II (52. %) consists of the majority of cases while others are Grade I (35.%), Grade III (10%) and Grade IV (3 %)

Conclusions: In present study percentage of drugs prescribed from national essential medicines list (NLEM) was found to be satisfactory but shows use of branded (Non-Generic) drugs. Drug utilization studies have the power to make objective evaluation as well as analysis of prescribers work and help them by giving feedback about their way of practice. This will help to determine and employ rational use of drugs among population. This study helps to give feedback to the treating doctors, by improving patient care by the way of rational prescribing of drugs.

Keywords: Acne Vulgaris. Drug Utilization Pattern, Rational Prescription, Tetracycline, Benzoyl Peroxide.

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1. INTRODUCTION

Acne vulgaris, generally known as acne, is a chronic inflammatory skin condition that affects 9.4% of people worldwide [1]. Acne affects about 90% of teenagers, and in half of those, the condition persists into adulthood [2]. Acne is thought to be brought on by a variety of elements, including Propionibacterium acnes, excessive sebum production by androgens, abnormal keratinization, inflammation, and obstruction of the sebaceous follicles [3]. Acne's severity varies depending on the size and type of lesions that have developed, which may involve postinflammatory pigmentary alterations and non-inflammatory (closed and open) and inflammatory lesions (papules, nodules, and pustules [4]. Even though acne is not life-threatening, it can yet leave physical and emotional scars. Anxiety, diminished self-esteem, depression, and suicidal thoughts are examples of emotional aftereffects. With hyperpigmentation, long-term physical effects might range from moderate scarring to severe scarring. The face, back, chest, and shoulders are among the body parts that are most commonly affected by acne [6]. Common chronic condition acne vulgaris may need long-term care. Adherence to medications is essential to managing acne; non-adherence is a common cause of treatment failure and can result in a poor quality of life [8][7].

Epidemiology
As of 2010, there were more than 650 million people suffering from acne around the globe, which represents 9.4% of the world's population[11]. In Western societies, it affects approximately 90% of people during adolescence, however it occasionally occurs earlier later in life and could persist even into adulthood [12]. Despite the low incidence of acne that appears for the first time between the ages of 21 and 25, it affects 40% of men and 54% of women over the age of 25[13].[11] with a reported 85% lifetime frequency.[13]
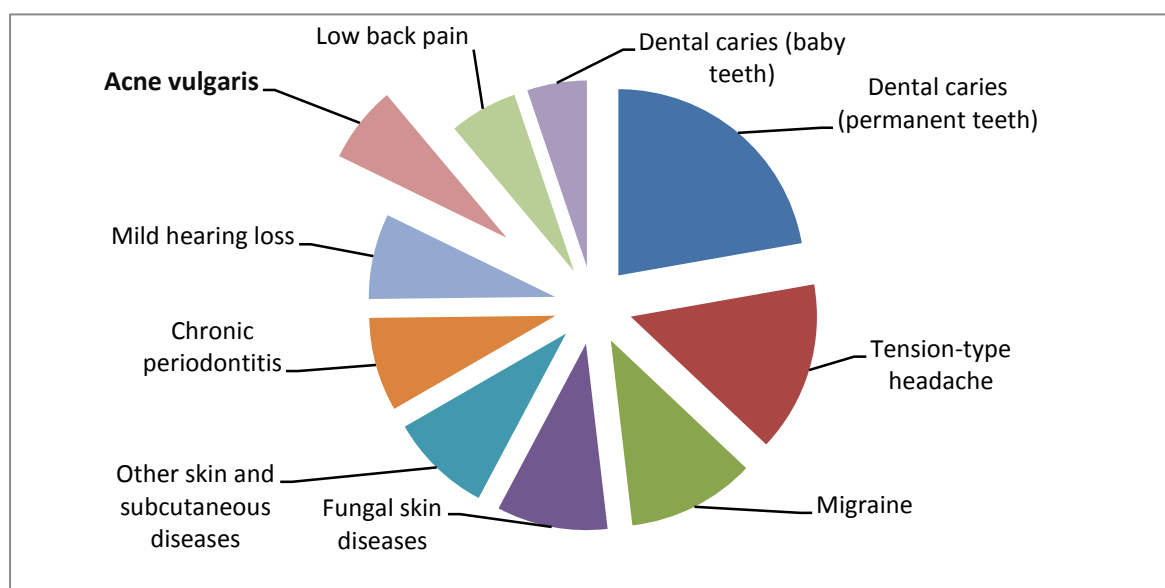
Around 3-5 million Australians (23% of the population) and 40–50 million Americans (16%) are both affected by acne [16]. People of Caucasian or American Indian origin are more likely than people of African descent to get severe acne[13].

Pathogenesis:

In the follicular epithelial lining, keratinocytes multiply and go through cellular differentiation alterations, which is the main pathophysiologic shift that results in acne. Normal desquamation is hampered by increased keratinization and increased cell adhesion. Sebum and cellular debris build up to block sebaceous follicles and create clinically invisible microcomedones [17]. An

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open comedo develops if the pressure of the impaction causes the outer section of the follicular opening to enlarge. Due to the possibility of follicular contents escaping to the skin surface when pressure from increased sebum production and cellular buildup develops, such lesions hardly ever become inflamed [18]. Increased pressure causes the follicular wall to break if the follicular opening is still small and a closed comedo forms, and the penetration of foreign material into the dermis triggers an inflammatory response. Depending on the depth and size of this occurrence, a pustule, papule, or nodule may develop [19]. Lesion development is mediated by bacterial colonisation and androgen-augmented sebocyte activity. The skin's 5--reductase breaks down testosterone, which is derived from the testicles in men and the ovaries and adrenals in women, into dihydrotestosterone (DHT), which in turn promotes sebum formation [17]. Increased sebum production dilutes the availability of linoleic acid and increases the production of interleukin-1-α, triggering hypercornification and thus comedogenesis [17][18]. Propionibacterium acnes can flourish in an environment that is lipid-rich and microaerophilic contributing to increased sebum production. This gram-positive rod secretes chemotactic substances that entice neutrophils, T cells, and macrophages, as well as proteases, hyaluronidases, lipases, and other enzymes [20]. The organism can survive intracellularly even after being swallowed by macrophages[21]. The follicular wall may be weakened by hydrolytic enzymes generated by macrophages, which could speed up rupture and the transformation of a comedone into an inflammatory lesion [18]. Prior to the follicular wall rupturing, inflammatory mediators cross the wall and enter the dermis to start the inflammatory process [22]. The activation of immune system components such as cell- and antibody-mediated processes as well as interleukins and tumour necrosis factor- by P. acnes all contribute to the inflammatory response [17]. Finally, acne patients may have increased cytochrome P450 1A1 activity due to a genetic predisposition, which lowers levels of protective endogenous retinoids [23].

Acne grading:
Any age can experience acne, and the severity can vary. With a wide clinical spectrum of comedones, papules, pustules, cysts, and/or nodules, female patients may more frequently develop lesions in the lower region of the face, particularly on the chin and jawline [24]. There are a variety of techniques for classifying the severity of acne vulgaris, including simple grading based on clinical examination, lesion counting, and techniques requiring complex equipment including photography, fluorescent photography, polarised light photography, video microscopy, and monitoring of sebum production. Grading is a process that gauges the severity of acne based on how prominent the lesions are, whether or not there is inflammation present, and how much of the body is affected [25]. For the evaluation of acne severity, more than 25 distinct grading schemes have been documented in the literature. Lehmann and others [26]. Carmen Thomas of Philadelphia was the first to use a score system for acne vulgaris. Beginning in the 1930s, she began keeping lesion counts in her office notes [27]. However, Pillsbury et al. (28) are credited with developing the first grading scheme. This assessment is based on an overall estimation of the type, number, and predominating lesion. The grading described in [28] is presented in Table 1.

Table 1: First grading system [28]

Grade	Description
1	Comedones and occasional small cysts confined to the face
2	Comedones with occasional pustules and small cysts confined to the face
3	Many comedones and small and large inflammatory

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	papules and pustules, more extensive but confined to the face
4	Many comedones and deep lesions tending to coalesce and canalize, and involving the face and the upper aspects of the trunk

Table 2: Grading system by James and Tisserand [29]

Grade	Description
Grade 1	Simple non-inflammatory acne comedones and a few Papules
Grade 2	Comedones, pastules and a few pustules
Grade 3	Larger inflammatory papules, pustules and a few cysts; a more severe form involving the face, neck and upper portions of the trunk
Grade 4	More severe, with cysts becoming confluent

In their assessment of acne therapy from 1958, James and Tisserand offered an alternate grading system (29). The grading scheme that they offered is shown in Table 3. If the affected skin area has a predominance of blackheads, whiteheads, and a few papules as specified in Table 2, grade 1 is chosen. Then, Grade 2 is determined if the patient's skin frequently exhibits blackheads, whiteheads, papules, and a few pustules. Grade 3 skin conditions include a few papules, pustules, and cysts on the face, neck, and upper trunk. Grade 4 status is assigned if the illness worsens and the cysts spread more widely.

Treatment

Topical treatment choices include topical retinoids (e.g., tretinoin, adapalene, and tazarotene), benzoyl peroxide (BPO), combinations of BPO and topical antibiotics (e.g., erythromycin and clindamycin), combinations of retinoids and antibiotics (e.g., clindamycin and tretinoin), combinations of benzoyl peroxides and retinoids (adapalene), salicylic acid, and azelaic acid. A standard treatment for the acne treatment was given by Gollnick *et al.*, 2003 is given in table 3[30] .Clindamycin is a lincosamide antibiotic used topically at a 1% concentration to treat inflammatory acne [31].

Table 3: Acne treatment

Type of acne	First line	Alternatives	Maintenance
Grade 1	Topical retinoid	Salicylic acid	Topical retinoid BPO or BPO/AB
Grade 2	Topical retinoid + BPO or BPO/antibiotic		Topical retinoid BPO or BPO/AB
Grade 3	Topical retinoid + oral antibiotic + BPO or BPO/AB or adapalene at night		Topical retinoid BPO or BPO/AB

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Grade 4	Oral isotretinoin	Oral antibiotic + topical retinoid + BPO or BPO/AB	Topical retinoid BPO or BPO/AB
AB: topical antibiotic; BPO: benzoyl peroxide.			

Antibiotics are a mainstay in the treatment of inflammatory acne. They work through several mechanisms to reduce the inflammatory response both directly and indirectly. Most importantly, they reduce the number of bacteria (P. *acnes*) in and around the follicle. They also reduce the inflammatory chemicals produced by white blood cells, and the free fatty acid concentration in the sebum, both of which reduce inflammation. Tetracycline antibiotics, such as tetracycline hydrochloride, doxycycline, and minocycline, are widely used for acne treatment. They work by reducing the population of acne-causing bacteria and have anti-inflammatory effects [32] . Tetracycline-based antibiotics are often considered as first-line oral treatment options for acne [33]

2. MATERIALS AND METHOD

Study Design
The study was conducted in a Lucknow tertiary care hospital over the spanned a period of six months using a hospital-based prospective observational technique focusing on acne vulgaris patients. The study setting encompassed both inpatient and outpatient divisions of hospital. The departments involved were the Department of Pharmacy, Integral University and the Department of Dermatology, Integral Institute of Medical Sciences and Research, Integral University. 100 people with acne vulgaris were included in the study that willingly participated and were enrolled based on predefined inclusion and exclusion criteria. Inclusion criteria encompassed patients of any age and gender visiting the OPD and IPD. On the other hand, exclusion criteria included patients who were not being treated for acne vulgaris or patients associated with others skin condition e.g. eruptive skin condition , patients unable to comply with the study requirements, as well as mentally retarded and unconscious patients and patients not willing to participate in the study. The sources of data for the study included physician prescribing records and the patients' medication profiles.

Data Collection
This study collected data using a structured questionnaire with open-ended questions to interview the participants. Prior to the commencement of the study, written consent was obtained from all participants. The questionnaire was designed to obtain patient profile data, such as age, sex, weight, patient address, and marital status. Additionally, information on prescribed drugs, including their generic/brand name, dose, and frequency, was also collected.

Participants were given weekly diary cards to record their daily drug intake to monitor adherence to the prescribed drug regimen. The data were collected in a structured data collection form.

Evaluation of parameters
The following parameters were evaluated: types of acne vulgaris drugs prescribed, gender distribution among diabetic patients, age distribution amongst diabetic patients, average number of acne vulgaris drugs per prescription, average age range of patients utilizing acne vulgaris drugs, comparison of acne vulgaris drugs prescribed in monotherapy vs. Fixed-dose combination therapy, and most commonly used drug of a particular class.

Statistical analysis
Descriptive statistics was applied to the collected data using Microsoft Excel software. Results will be expressed in percentages. ANOVA / Student's t- test will be applied on the collected data to evaluate the statistical significance (P-value). A statistical significance level of less than 0.05 ($p < 0.05$) was considered as indicating statistical significance.

Ethical considerations

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The study was complied fully with the WHO guidelines and will be done after obtaining approval from Institutional Research and Ethics Committee and Institutional review board with approval no IEC/IIMS&R/2021/xxxx. The Protocol and the corresponding Informed Consent Form (ICF) will be submitted to the Integral Institute of Medical Sciences and Research (IIMSR) hospital, Integral University for the approval of conduct of this study.

Informed consent form
An oral and written consent was obtained from parents before the participation of the subjects in the study

3. RESULTS

Demographic Data
Data was collected at the Integral hospital for the time period of 6-months based on inclusion and exclusion criteria. Total 100 patients were participated in our study. In the study, majority populations were female patients (58%) as compare to male patients (42%). It was found that lowest numbers of patients from the age group 30-40 years and the highest number of patient from the age group 15 -25 years [Table 4].

Table 4: Demographic Data of Study Participant

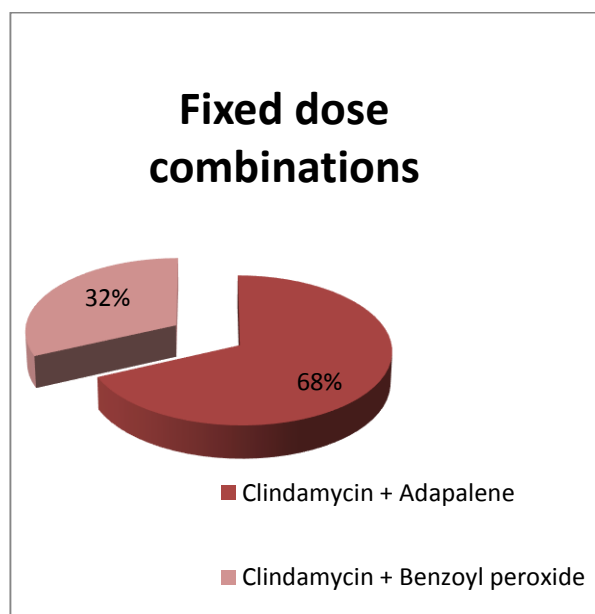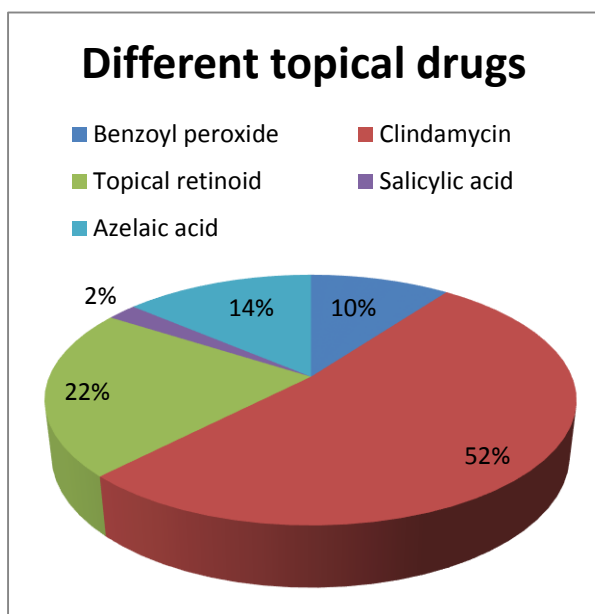| Age group (in years)	Number	Percentage
>15	10	10%
15-20	30	30%
21-25	25	25%
26-30	16	16%
31-35	7	7%
36-40	6	6%
<40	6	6%

Analysis of prescription
This study analyzed the prescribing pattern of 100 prescriptions. Among the prescriptions analyzed, it was observed that average numbers of drugs per prescription were 2.41%. A total of 241 drugs were prescribed, out of which 57% were topical and 43% were oral drug. It was observed that most commonly prescribed oral drugs were from tetracycline class (58%) [table 5] and clindamycin (52%) as most commonly used topical antibiotic [figure 4]. The most commonly prescribed topical combination preparation was clindamycinn + Adapalene 68% [figures 5].

Table 5: Analysis of prescription

Different oral drugs	No. of encounter (n =103)	Different topical drugs	No. of encounter (n =138)
Azithromycin	30	Benzoyl peroxide	14
Doxycycline	24	Topical retinoid	30
Minocycline	17	Clindamycin	72
Tetracycline	9	Salicylic acid	3
Isotretinoin	24	Azelaic acid	19

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Different topical drugs

- Benzoyl peroxide
- Clindamycin
- Topical retinoid
- Salicylic acid
- Azelaic acid

2%
14%
10%
22%
52%

Fixed dose combinations

32%
68%

- Clindamycin + Adapalene
- Clindamycin + Benzoyl peroxide

4. DISCUSSION

The project, titled "Study of Drug Utilization Pattern for Acne Vulgaris in the Department of Dermatology at Integral Institute of Medical Sciences and Research" was conducted at IIMSR, Lucknow from November 2021 to April 2022. Over a period of six months study, it was noted in our study that over 1000 individuals (suffering from various diseases) visited the inpatient department. Among them 100 patients were chosen for the study based on inclusion and exclusion criteria.

In the population we found, female patients made up the majority (58%) compared to male patients (42%). The study population revealed that the age groups of 15 to 25 years had the largest percentages of patients and the 30 to 40 year age group had the lowest numbers of patients [Table 3].

In our study, demographic data revealed that the percentage of females (58%) with acne vulgaris was higher than that of males (42%). This indicates that there was a higher proportion of female patients seeking treatment. Several factors contribute to the difference in acne prevalence between males and females. Hormonal variations, such as increased androgen levels during puberty, can play a significant role in the development of

acne. Additionally, factors like genetics, skin type, and lifestyle choices can also contribute to the occurrence and severity of acne.

This finding aligns with common observations regarding the age distribution of acne. Acne was typically more prevalent during adolescence and early adulthood, which corresponds to the 15-25 years age range mentioned. During this period, hormonal changes, particularly the increase in androgen levels, can stimulate the production of sebum and lead to the development of acne.

As individuals age and progress into their 30s and beyond, hormonal fluctuations tend to stabilize, resulting in a decrease in the prevalence of acne. However, it is important to note that acne can still affect individuals beyond their teenage years, and some adults may continue to experience acne-related issues.

The study found that pharmaceuticals were administered to treat acne, with topical therapies accounting for 57% of prescriptions and oral meds for 43%.
Creams, gels, and lotions that are applied directly to the skin are the most common types of topical treatments for acne. They frequently include active chemicals such salicylic acid, retinoids, benzoyl peroxide, and antibiotics.

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These topically applied medications function by calming inflammation, clearing clogged pores, and limiting bacterial growth on the skin.

On the other hand, oral drugs are swallowed whole in the form of pills or capsules. They are frequently used for cases of acne that are moderate to severe or don't react well to topical medications alone. Antibiotics, hormonal contraceptives (for females), isotretinoin (Accutane), and other drugs are frequently prescribed orally to treat acne. The underlying causes of acne, such as bacteria, hormone imbalances, or excessive sebum production, are the focus of these drugs' mechanism of action. However, it's important to note that the choice between topical and oral medications can vary depending on the severity of acne, individual patient factors, and the judgment of the prescribing healthcare professional.

In our study the most commonly prescribed oral drug for the treatment of acne was from the tetracycline class, accounting for 58% of the prescriptions. Azithromycin was the second most commonly prescribed oral drug, accounting for 29% of the prescriptions. Lastly, isotretinoin was prescribed in 23% of the cases.

Tetracycline antibiotics, such as doxycycline and minocycline, are often used in the treatment of acne due to their ability to target bacteria and reduce inflammation. They work by inhibiting the growth of *Propionibacterium acnes*, a bacteria commonly associated with acne. Tetracyclines also possess anti-inflammatory properties, which can help alleviate acne symptoms. Azithromycin, a macrolide antibiotic, can also be prescribed for acne treatment. It works by suppressing bacterial growth and reducing inflammation.

Isotretinoin, also known by the brand name Accutane, is a potent oral medication reserved for severe or resistant cases of acne. Although it has possible side effects and is quite effective, strict monitoring and attention to safety protocols are still necessary. As well as controlling sebum production and

inflammation, isotretinoin also slows the development of germs that cause acne. The distribution of these oral drugs reveals that tetracyclines were the most often used acne treatment by medical professionals in the study population, followed by azithromycin and isotretinoin.

The results of the study showed that 52% of the prescriptions for topical antibiotics used to treat acne were for clindamycin. Among the other topical treatments, retinoids were used in 22% of the cases. Retinoids, such as tretinoin or adapalene, are derivatives of vitamin A and are effective in promoting skin cell turnover, unclogging pores, and reducing acne lesions.

Azelaic acid was used in 14% of the cases. Azelaic acid is a naturally occurring acid that has antimicrobial and anti-inflammatory properties. It can help to normalize the skin's shedding process and reduce the formation of comedones (clogged pores).

Benzoyl peroxide (BP) was used in 10% of the cases. BP is an antibacterial agent that helps to kill acne-causing bacteria and reduce inflammation. It is available in various formulations, such as creams, gels, or washes.

Salicylic acid, a keratolytic agent that helps to exfoliate the skin and unclog pores, was the least commonly used topical treatment at 2%. The most frequently prescribed topical treatments for treating acne in the study population were clindamycin, retinoids, and azelaic acid. Salicylic acid and benzoyl peroxide were the least frequently used treatments.

In our study the most commonly prescribed topical combination preparation was clindamycin and adapalene, accounting for 68% of the prescriptions. This combination involves the use of clindamycin, an antibiotic, and adapalene, a retinoid. Clindamycin helps to reduce bacterial growth, while adapalene promotes skin cell turnover and unclogs pores. This combination can provide comprehensive treatment for acne by addressing both bacteria and inflammation.

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The second most commonly prescribed combination was clindamycin + benzoyl peroxide (BP), accounting for 32% of the prescriptions. This combination utilizes the antibacterial properties of clindamycin and benzoyl peroxide to target acne-causing bacteria and reduce inflammation. Benzoyl peroxide also helps to unclog pores and prevent future acne breakouts.

5. CONCLUSION

In present study percentage of drugs prescribed from national essential medicines list (NLEM) was found to be satisfactory but shows use of branded (Non-Generic) drugs. Drug utilization studies can be used as further basis for the prescribing doctors. Such periodic audits must conduct to reduce errors, rationalize prescriptions and provide effective treatment of acne vulgaris. Drug utilization studies have the power to make objective evaluation as well as analysis of prescribers work and help them by giving feedback about their way of practice. This will help to determine and employ rational use of drugs among population. The hospital administration can implement a formulary into the hospital so dermatologist, treating physicians, or concern prescribers should restrict their prescribing for effective therapy to the patients. Prescriber must prescribe the drugs in generic names. This study helps to give feedback to the treating doctors, by improving patient care by the way of rational prescribing of drugs. It is recommended that there is a need for all doctors to work together to establish rational and practical protocol for various clinical conditions and also to take educational initiative to encourage appropriate and rational use of drugs.

Limitations
Our study has many limitations. The study was careried out over a six-month period, and the seasonal variations in disease pattern and drug prescribing pattern were not considered. Furthermore, the number of patient was low and the study was restricted only one hospital, hence the result cannot be considered representatives of the whole country. However, in the spite of all these limitations, our study highlighted some rational prescribing practices

Confidentiality of Data
The data identifying each study subject by name was kept confidential and accessible to the study personnel and if necessary, to the Integral Institute of Medical Sciences and Research (IIMSR) hospital Institutional Review Board. The Protocol and the corresponding Informed Consent Form (ICF) was submitted to the Integral Institute of Medical Sciences and Research (IIMSR) hospital, integral university for the approval of conduct of this study.

Author Contributions: All authors have accepted responsibility for the entire content of this manuscript and approved its submission.

Conflict of Interest: Author states no conflict of interest.

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