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## Efficacy And Safety Of Oral Clindamycin In Comparison With Doxycycline In Acne Vulgaris.

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### ABSTRACT

Acne vulgaris is a chronic inflammatory disease of pilosebaceous units. It is a common skin disorder affecting both boys and girls in the adolescent age group and also extends into the post adolescent age group. Commonly it is due to formation of obstructing horny plugs in hair follicles, resulting in inflammation around the hair follicles, causing tissue destruction and scar formation. Modern medicine also prescribes various drugs, which have been found to be useful in controlling this disorder. All of them have been found to be useful to various extents. Topical drug therapy has been the mainstay and some drugs, for example, tetracycline is given orally. Efficacy of oral clindamycin in comparison with doxycycline in mild to moderate cases of acne vulgaris. The study is conducted as four different trials. In each trial totally 60 patients are selected and are randomly divided in to 2 groups, group A and B. In this study, only grade I (mild) & grade II (moderate) patients are included and grade III and grade IV patients are not included. The effect of drugs in reducing the number of comedons, papules and pustules in all the four trial groups are recorded before starting treatment and at the end of every week for six weeks. The study has proved that a low dose of 50 mg of oral Clindamycin administered once a day for four weeks produces good results in acne vulgaris. The good results are obtained without unwanted adverse reactions. For many infections 150 to 300 mg are given 3 - 4 times a day produces many adverse effects. In this trial the low dose of 50 mg used is not only highly effective, but also has not produced any significant adverse reactions. So far, the Clindamycin has only been used topically for acne vulgaris. This study encourages the use of low dose oral Clindamycin in acne vulgaris.

**Keywords:** Acne Vulgaris; Clindamycin Cost-effective Analysis; Doxycycline.

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## INTRODUCTION

Acne vulgaris is a chronic inflammatory disease of pilosebaceous units. It is a common skin disorder affecting both boys and girls in the adolescent age group and also extends into the post adolescent age group [1]. Commonly it is due to formation of obstructing horny plugs in hair follicles, resulting in inflammation around the hair follicles, causing tissue destruction and scar formation [2]. This problem is present universally and affects people of all socio economic groups. With the improvement in the living status, awareness about acne is more among the affected age group causing psychological problems too. From time immemorial, various remedies have been suggested and followed by Ayurvedic, Siddha, Unani practitioners and native healers present in various parts of the world [3]. The scientific evidence of improvement has not been documented yet. Modern medicine also prescribes various drugs, which have been found to be useful in controlling this disorder. All of them have been found to be useful to various extents [4]. Topical drug therapy has been the mainstay and some drugs, for example, tetracycline is given orally [5]. Since the condition results in scar formation and disfigurement in young boys and girls, it is associated with psychological problems causing great distress [6].

## METHODS

The Study was started after getting the approval from institutional ethical committee. Patients were included only after obtaining the informed written consent. In patients who were less than 18 years old, the consent was obtained from parents also.

### Inclusion Criteria

- Having mild to moderate acne vulgaris with the lesions only on cheek, forehead, chin, nose and neck (above clavicle).
- Both males and females of 15 years to 25 years.
- Willing to give written informed consent.
- Suffering from acne vulgaris for three or more months.
- Not under drug therapy for acne vulgaris.
- Not suffering from any systemic illness.

### Exclusion Criteria

- Patients who are
- Having severe acne vulgaris
- Below 15 years and above 25 years.
- Suffering from systemic illness like cardiac valvular lesions, Diabetes mellitus, Hypertension and congenital anomalies.
- Not willing to give informed written consent.
- With the history of hypersensitivity to antimicrobials.

The study is conducted as four different trials. In each trial totally 60 patients are selected and are randomly divided in to 2 groups, group A and B.

### Trial I

In trial I, 60 patients suffering from mild acne vulgaris are included and are randomly allotted in to group A and B, with 30 patients in each group. Group A patients are treated with oral Doxycycline 100 mg, once daily, in the morning, after food, for four weeks. Group B patients are treated with oral Clindamycin 50 mg once daily in the morning, after food, for four weeks. The patients are assessed before starting drug therapy and after drug administration, at the end of 1st week, 2nd week, 3rd week and at the end of 4th week. The patients are also assessed during the follow up visits at the end of 5th and 6th weeks.

### Trial II

In this trial also, 60 patients suffering from mild acne vulgaris are included and are randomly allotted in to group A and B, with 30 patients in each group. But here, Group A patients are treated with

5% topical Benzoyl peroxide applied during bed time every day for 4 weeks, in addition to oral Doxycycline 100 mg given once daily, in the morning, after food, every day for four weeks. Group B patients are treated with 5% topical Benzoyl peroxide applied during bed time every day for 4 weeks, in addition to oral clindamycin 50 mg given once daily, in the morning, after food, every day for four weeks. patients in both the groups are assessed before starting therapy and at the end of every week as done in Trial I.

### **Trial III**

In Trial III, 60 patients suffering from moderate acne vulgaris are included and are randomly allotted in to group A and B, with 30 patients in each group. Group A patients are treated with oral Doxycycline 100 mg, once daily, in the morning, after food, every day for four weeks. Group B patients are treated with oral clindamycin 50 mg once daily in the morning, after food, every day for four weeks. The patients are assessed before and after drug therapy in the similar way followed in trial I and II.

### **Trial IV**

In trial IV, like trial III, 60 patients suffering from moderate acne vulgaris are included and are randomly allotted in to group A and B, with 30 patients in each group. Here Group A patients are treated with 5% topical Benzoyl peroxide applied during bed time every day for 4 weeks, in addition to oral Doxycycline 100 mg given once daily, in the morning, after food, every day for four weeks. Group B patients are treated with 5% topical Benzoyl peroxide applied during bed time every day for 4 weeks, in addition to oral clindamycin 50 mg given once daily, in the morning, after food, every day for four weeks.

### **Assesment Criteria**

Acne vulgaris is classified into Grade I, II, III and IV depending upon the presence of comedons, papules and pustules.

Grade I (mild)	- Comedons & occasional papules.
Grade II (moderate)	- Comedons, papules & few pustules.
Grade III (severe)	- Pustules, nodules & abscesses.
Grade IV (cystic)	-Very severe form consists of cysts,

### **Abscesses & Scarring.**

In this study, only grade I (mild) & grade II (moderate) patients are included and grade III and grade IV patients are not included. The effect of drugs in reducing the number of comedons, papules and pustules in all the four trial groups are recorded before starting treatment and at the end of every week for six weeks. The results are assessed both clinically and statistically in all the four trials.

## **RESULTS**

The results of the study conducted to evaluate the safety and efficacy of oral dose of 50 mg of Clindamycin administered daily for a period of four weeks in comparison with oral Doxycycline are presented and analysed.

The purpose of using topical Benzoyl peroxide 5% cream is to see if the benefit arising out of combination therapy is better than single drug therapy or not.

### **Results Of Trial I**

#### **The Effect Of Drugs On Comedons In Mild Cases Of Acne**

When Doxycycline is administered orally for four weeks in 30 patients, on zero visit that is before drug administration, the arithmetical mean of number of comedons was 4.40 and this has come down to 3.06 at the end of six weeks.

**Table 1: No. of comedons in each patient in group A of trial I**

S.No.	visit 0	visit 1	visit 2	visit 3	visit 4	visit 5	visit 6
1	4	4	4	4	3	3	4
2	4	3	3	4	3	3	3
3	5	3	3	4	3	4	4
4	4	4	4	3	3	2	3
5	5	3	3	4	4	4	2
6	3	3	3	4	3	3	3
7	5	5	4	2	3	4	3
8	5	5	3	4	4	3	2
9	4	4	3	4	2	2	3
10	5	4	4	4	4	3	3
11	4	3	4	2	3	3	4
12	4	3	4	3	4	2	3
13	4	5	5	3	3	3	4
14	3	5	4	5	2	3	3
15	5	4	3	3	3	4	2
16	5	4	4	3	3	3	3
17	5	5	4	4	2	4	3
18	5	5	5	4	3	3	3
19	4	4	4	3	3	2	4
20	5	3	4	4	4	3	3
21	4	4	4	3	4	3	4
22	3	5	5	3	3	2	3
23	5	4	3	4	4	3	2
24	5	3	5	3	3	3	3
25	4	5	5	3	4	4	3
26	4	4	3	4	4	4	2
27	5	3	3	3	3	3	3
28	5	5	4	3	2	4	3
29	4	4	4	3	3	3	4
30	5	4	3	2	3	4	3
Mean	4.4	4	3.8	3.4	3.16	3.13	3.06

In Clindamycin administered group, the arithmetical mean of number of comedons, 4.33 on '0' visit that is before drug administration has come down to 2.83 after 6 weeks of drug administration.

**Table 2: No. of comedons in each patient in group B of trial I**

S.No.	visit 0	visit 1	visit 2	visit 3	visit 4	visit 5	visit 6
1	4	3	4	4	3	3	3
2	5	3	5	4	4	2	4
3	4	5	3	3	3	3	3
4	4	1	4	3	2	3	2
5	4	1	4	1	2	2	3
6	3	4	3	4	2	3	3
7	5	3	4	4	3	4	2
8	5	3	4	3	3	3	4
9	5	5	4	1	2	2	2
10	5	1	1	3	4	3	4

11	4	2	4	5	3	4	3
12	5	4	4	3	4	3	3
13	4	5	1	1	3	3	3
14	3	5	4	4	2	4	4
15	5	4	3	3	4	3	3
16	5	3	2	2	4	2	2
17	4	2	1	2	3	3	2
18	4	5	3	3	4	4	4
19	5	4	4	3	2	1	3
20	5	3	3	4	3	3	2
21	4	1	3	2	4	3	3
22	5	4	4	1	3	4	3
23	4	5	3	2	2	2	3
24	3	4	1	3	4	2	2
25	5	4	2	4	3	3	3
26	5	2	3	3	1	4	2
27	4	5	4	3	2	3	1
28	4	4	2	3	2	3	4
29	5	3	1	4	3	4	3
30	3	5	4	3	2	3	2
Mean	4.33	3.43	3.06	2.93	2.86	2.96	2.83

**The Effect Of Drugs On Papules In Mild Cases Of Acne**

In Doxycycline administered group the arithmetical mean of number of papules in 30 patients on '0' visit that is before drug administration was 3.30 and it has come down to 2.2 at the end of sixth week.

**Table 3: No. of papules in each patient in group A of trial I**

S.No.	visit 0	visit 1	visit 2	visit 3	visit 4	visit 5	visit 6
1	4	2	2	3	2	2	1
2	4	3	1	2	3	3	2
3	3	3	2	3	1	2	2
4	4	2	1	3	3	1	2
5	3	2	2	2	1	1	2
6	4	3	3	3	2	3	3
7	2	3	2	2	3	2	3
8	3	2	3	1	1	3	2
9	4	4	3	2	2	2	3
10	2	2	3	1	2	3	1
11	3	3	2	2	3	3	2
12	4	3	4	3	1	2	3
13	3	4	2	3	3	2	2
14	3	2	4	1	2	3	2
15	4	3	3	2	1	2	2
16	4	2	2	3	3	3	3
17	3	3	4	2	2	2	1
18	4	3	3	3	2	2	2
19	2	2	1	3	3	2	2

20	3	3	2	3	2	2	3
21	4	4	2	3	2	3	2
22	3	3	2	2	3	2	2
23	4	2	3	2	4	1	2
24	4	3	2	3	3	2	3
25	3	3	3	3	2	2	3
26	4	2	2	2	2	2	2
27	2	3	3	3	3	3	3
28	3	2	2	1	2	2	3
29	4	4	4	2	2	3	1
30	2	2	3	2	2	0	2
Mean	3.3	2.73	2.5	2.33	2.23	2.16	2.2

In the case of Clindamycin administered group the arithmetical mean of number of the papules in 30 patients on '0' visit that is before drug administration was 3.36 and it has very significantly come down to 1.9 at the end of sixth visit.

**Table 4: No. of papules in each patient in group B of trial I**

S.No.	visit 0	visit 1	visit 2	visit 3	visit 4	visit 5	visit 6
1	2	3	1	2	2	1	1
2	3	2	2	3	3	3	2
3	4	4	2	1	1	2	2
4	2	2	3	2	2	1	3
5	3	3	2	3	2	3	2
6	4	3	2	1	3	2	0
7	3	1	2	2	2	2	2
8	3	2	2	2	3	1	1
9	4	3	2	3	1	3	1
10	4	2	3	1	0	0	2
11	3	1	2	2	1	2	2
12	4	3	2	2	1	1	3
13	4	2	3	1	2	1	2
14	3	3	1	2	1	2	2
15	4	1	2	2	2	1	2
16	4	3	2	2	2	2	2
17	3	2	2	1	3	2	3
18	4	3	2	2	1	3	3
19	4	3	3	2	3	2	1
20	3	2	2	3	2	3	0
21	4	2	3	1	1	3	2
22	2	2	2	2	3	1	2
23	3	3	2	3	2	3	3
24	4	3	2	3	2	2	2
25	3	2	3	2	1	2	1
26	3	2	2	4	2	3	2
27	4	3	2	2	1	3	2

28	3	2	2	1	3	1	2
29	3	3	3	2	1	2	3
30	4	2	0	3	2	1	2
Mean	3.36	2.4	2.1	2.06	1.83	1.93	1.9

**Results Of Trial II**

**The Effect Of Drugs On Comedons In Mild Cases Of Acne**

The arithmetical mean of the number of comedons in one group of thirty patients who receive oral Doxycycline along with topical Benzoyl peroxide was 4.33 on '0'visit that is before starting therapy. The arithmetic mean at the end of sixth visit has come down to 2.0.

**Table 5: No. of comedons in each patient in group A of trial II**

S.No.	visit 0	visit 1	visit 2	visit 3	visit 4	visit 5	visit 6
1	4	4	3	3	3	3	3
2	4	4	3	1	2	2	3
3	3	3	4	3	3	2	0
4	5	3	4	1	3	0	3
5	5	5	4	2	4	3	1
6	5	5	5	3	3	2	3
7	5	4	4	1	4	3	2
8	4	4	3	4	1	0	3
9	5	5	2	4	2	3	1
10	4	5	4	2	3	3	3
11	3	4	3	1	0	4	2
12	5	3	4	1	1	3	2
13	5	4	3	2	3	0	3
14	4	5	3	0	4	1	2
15	3	3	1	1	3	3	2
16	5	3	3	3	1	3	0
17	5	1	3	3	1	2	2
18	4	4	3	2	2	3	2
19	4	3	2	3	3	1	1
20	5	3	3	2	3	3	4
21	5	5	3	3	1	2	1
22	4	1	4	1	2	3	3
23	5	4	1	2	1	2	2
24	4	4	3	1	0	1	2
25	3	2	5	3	2	3	1
26	5	4	4	2	3	2	1
27	5	4	2	3	0	3	2
28	4	1	1	3	2	1	3
29	3	3	1	1	1	0	2
30	5	4	2	0	2	2	1
Mean	4.33	3.56	3	2.03	2.1	2.1	2

In other group which was treated with oral Clindamycin along with topical Benzoyl peroxide the arithmetical mean come down to 1.1 at the end of sixth visit from 4.6 the mean before treatment.

**Table 6: No. of comedons in each patient in group B of trial II**

S.No.	visit 0	visit 1	visit 2	visit 3	visit 4	visit 5	visit 6
1	3	3	4	2	1	0	2
2	5	4	3	3	3	0	3
3	5	4	2	3	2	1	0
4	4	3	3	1	1	0	1
5	4	4	3	3	1	1	0
6	5	3	4	0	1	3	1
7	5	3	3	3	3	2	0
8	4	4	4	2	0	1	0
9	5	3	3	1	0	0	0
10	4	4	2	2	0	1	1
11	5	4	3	0	1	1	1
12	5	4	2	1	1	2	1
13	5	5	2	0	1	0	1
14	5	4	3	0	0	1	1
15	4	3	3	3	1	1	1
16	5	4	4	2	1	2	2
17	5	4	4	1	1	1	3
18	5	3	2	1	1	1	1
19	5	4	4	1	2	1	3
20	4	5	3	3	1	2	1
21	5	3	4	2	2	2	1
22	5	4	3	0	1	0	2
23	3	3	5	2	0	2	0
24	5	3	3	0	3	1	0
25	5	3	3	2	0	0	3
26	4	4	4	1	1	1	0
27	5	3	3	2	2	2	0
28	5	2	2	0	1	0	2
29	5	4	2	2	0	1	2
30	4	2	3	1	0	1	0
Mean	4.6	3.53	3.1	1.46	1.06	1.03	1.1

**The Effect Of Drugs On Papules In Mild Cases**

The arithmetical mean of the number of papules in one group of thirty patients who receive oral Doxycycline along with topical Benzoylperoxide was 3.56 on '0'visit that is before starting therapy. The arithmetic mean at the end of sixth visit hss come down to 1.6.

**Table 7: No. of papules in each patient in group A of trial II**

S.No.	visit 0	visit 1	visit 2	visit 3	visit 4	visit 5	visit 6
1	4	2	3	2	2	1	2
2	4	3	1	3	2	1	2
3	3	3	2	1	0	2	3
4	4	1	2	2	3	1	2
5	4	2	3	2	2	2	3
6	3	3	1	1	2	2	3
7	4	2	2	2	2	3	2



8	4	1	2	2	1	2	2
9	3	3	2	2	2	3	1
10	4	2	2	1	0	3	3
11	4	3	2	2	2	2	0
12	3	1	2	2	1	2	2
13	4	3	0	3	1	1	1
14	3	2	1	2	2	3	1
15	4	3	3	2	1	0	1
16	3	2	2	2	2	2	0
17	3	1	1	2	2	2	2
18	4	3	2	0	3	1	2
19	4	2	2	3	2	2	1
20	3	3	3	2	3	0	2
21	4	1	1	2	3	0	1
22	4	3	3	2	2	1	2
23	3	2	2	1	2	1	1
24	4	3	2	2	1	2	1
25	4	3	2	2	0	0	2
26	3	3	2	0	0	2	1
27	3	3	3	1	2	2	1
28	4	2	1	2	1	1	1
29	3	2	2	2	1	1	2
30	3	2	2	0	1	0	1
Mean	3.56	2.3	1.93	1.73	1.6	1.5	1.6

In case of papules, the group of thirty patients treated with oral Clindamycin along with topical Benzoylperoxide the corresponding values are 3.56 before therapy and 0.86 at the end of sixth week. This is also clinically significant.

**Table 8: No. of papules in each patient in group B of trial II**

S.No.	visit 0	visit 1	visit 2	visit 3	visit 4	visit 5	visit 6
1	4	2	1	1	1	1	0
2	4	3	3	2	0	1	1
3	3	1	0	0	2	2	1
4	4	2	2	2	0	2	0
5	4	2	2	0	2	1	0
6	3	1	1	2	1	1	2
7	4	2	2	0	1	0	1
8	4	2	0	2	0	2	2
9	3	3	0	1	2	1	1
10	3	4	1	2	0	1	0
11	4	3	1	0	2	2	2
12	3	2	2	1	2	0	0
13	3	2	0	2	0	0	1
14	4	3	2	1	0	0	1
15	3	2	2	1	0	0	2
16	3	2	1	0	2	1	1
17	4	2	3	2	0	1	2

18	4	2	2	3	1	1	2
19	3	3	3	3	1	0	0
20	4	2	3	2	0	0	1
21	3	2	2	2	0	1	0
22	4	2	2	1	0	0	1
23	3	0	1	1	1	0	1
24	3	2	3	0	2	1	1
25	4	3	0	2	0	1	0
26	4	2	2	2	0	0	1
27	3	1	2	1	0	0	1
28	4	2	1	2	0	2	0
29	4	2	2	0	0	0	0
30	4	1	2	1	1	0	1
Mean	3.56	2.06	1.6	1.3	0.7	0.73	0.86

**Results Of Trial III**

**The Effect Of Drugs On Comedons In Moderate Cases Of Acne**

Here in the group of 30 patients who received oral Doxycycline, the arithmetical mean of number of comedons before therapy 4.73 and at the end of sixth week it is 3.06.

**Table 9: No. of comedons in each patient in group A of trial III**

S.No.	visit 0	visit 1	visit 2	visit 3	visit 4	visit 5	visit 6
1	4	5	4	3	2	3	3
2	5	3	4	3	3	4	3
3	5	5	5	2	3	3	3
4	4	5	3	3	5	2	4
5	5	4	4	3	3	3	3
6	4	4	3	4	3	3	4
7	4	4	4	3	4	2	4
8	4	4	3	4	4	3	2
9	4	5	3	4	3	3	3
10	5	5	4	4	4	4	3
11	5	4	4	3	3	3	2
12	5	4	3	4	3	4	3
13	5	4	5	4	4	3	3
14	4	5	4	5	3	4	2
15	5	4	3	3	3	4	3
16	5	5	4	4	3	2	3
17	5	5	4	4	4	4	4
18	5	4	3	2	3	3	3
19	5	3	4	3	3	4	3
20	4	5	4	3	4	3	4
21	5	4	3	4	2	2	3
22	5	4	4	3	4	3	4
23	5	4	5	3	3	3	3
24	5	3	4	3	2	2	4
25	5	3	3	4	3	3	3
26	5	5	5	3	2	4	3

27	5	4	4	3	3	4	2
28	5	3	3	2	3	3	3
29	5	4	5	3	2	2	3
30	5	4	4	4	3	3	2
Mean	4.73	4.16	3.83	3.33	3.13	3.1	3.06

In another group of 30 patients who received only oral clindamycin the arithmetical mean is 4.66, before therapy has come down to 2.66 at the end sixth week.

**Table 10: No. of comedons in each patient in group B of trial III**

S.No.	visit 0	visit 1	visit 2	visit 3	visit 4	visit 5	visit 6
1	4	4	3	2	2	3	2
2	4	1	4	3	3	2	3
3	5	4	4	3	1	3	3
4	5	2	3	4	4	2	2
5	5	5	5	2	4	3	3
6	5	4	4	3	3	4	3
7	4	3	3	3	4	4	1
8	5	5	4	4	3	2	3
9	5	5	4	3	3	1	3
10	5	2	3	3	1	3	4
11	5	4	4	2	3	4	3
12	5	3	4	3	3	3	1
13	4	3	3	3	3	2	3
14	5	4	4	4	1	3	4
15	5	5	5	3	3	1	3
16	4	4	4	4	3	2	1
17	5	4	3	2	4	3	4
18	4	5	5	4	1	3	2
19	4	5	3	2	4	4	3
20	4	4	4	4	3	3	3
21	4	5	3	4	4	1	2
22	5	4	4	5	3	3	3
23	5	5	3	3	3	4	2
24	5	4	3	4	4	4	2
25	5	5	4	4	3	2	3
26	4	5	4	2	3	1	3
27	5	4	3	3	3	3	2
28	5	4	5	3	4	4	3
29	5	5	4	4	3	3	3
30	5	4	3	2	3	2	3
Mean	4.66	4.03	3.73	3.16	2.96	2.73	2.66

**The Effect Of Drugs On Papules In Moderate Cases Of Acne**

In case of Doxycycline treated group the arithmetical mean of papules on '0' visit that is before drug therapy was 3.56 and at the end sixth week it was 2.36.

**Table 11: No. of papules in each patient in group A of trial III**

S.No.	visit 0	visit 1	visit 2	visit 3	visit 4	visit 5	visit 6
1	4	3	3	3	2	3	2
2	3	3	3	2	3	2	3
3	4	2	2	3	1	3	2
4	4	4	4	2	2	2	2
5	3	2	2	1	2	3	2
6	4	3	4	2	3	3	3
7	3	3	3	1	1	4	1
8	4	4	2	2	3	2	2
9	4	2	4	3	2	3	2
10	4	3	3	3	1	2	3
11	3	4	1	1	3	3	2
12	4	3	2	2	2	2	2
13	2	3	2	3	2	2	2
14	3	2	2	2	3	2	3
15	4	3	3	3	2	2	3
16	3	4	2	3	2	2	2
17	4	3	3	3	3	1	3
18	4	2	2	4	3	4	3
19	3	3	1	3	3	3	3
20	4	3	2	2	2	2	3
21	4	4	3	3	2	3	2
22	4	2	2	1	3	2	3
23	4	3	3	2	2	3	1
24	4	3	3	2	1	3	2
25	3	4	3	4	3	2	3
26	4	4	2	2	2	2	2
27	3	4	4	1	2	3	4
28	4	4	2	2	3	1	2
29	3	2	4	4	4	2	2
30	4	2	3	2	3	2	2
Mean	3.6	3.03	2.63	2.36	2.33	2.43	2.36

In Cindamycin treated group the corresponding values are 3.53 and 1.96 before therapy and at the end of sixth week respectively.

**Table 12: No. of papules in each patient in group B of trial III**

S.No.	visit 0	visit 1	visit 2	visit 3	visit 4	visit 5	visit 6
1	4	4	3	1	2	1	1
2	3	2	3	2	1	1	2
3	3	3	3	1	1	1	1
4	4	3	3	2	3	3	1
5	4	4	2	1	2	2	2
6	3	3	3	2	2	3	2
7	4	3	1	3	3	2	2
8	2	2	2	3	2	3	3
9	3	3	2	2	1	3	3
10	4	3	4	2	3	2	2

11	3	2	2	3	2	2	3
12	4	3	2	2	2	1	3
13	4	4	2	3	3	1	1
14	3	3	1	3	1	2	3
15	4	2	2	1	3	2	1
16	4	3	2	2	3	3	1
17	3	2	1	3	1	2	1
18	4	3	2	2	2	3	2
19	4	3	3	1	2	2	2
20	2	2	2	1	1	2	3
21	3	3	3	3	3	2	1
22	4	4	3	3	2	2	2
23	3	3	3	1	2	2	2
24	4	3	3	2	1	1	3
25	4	3	3	1	2	1	2
26	3	3	2	2	2	1	2
27	4	2	3	2	1	2	3
28	4	4	3	3	0	2	2
29	4	2	3	2	2	3	1
30	4	2	2	3	1	1	2
Mean	3.53	2.86	2.43	2.06	1.86	1.93	1.96

**The Effect Of Drugs On Pustules In Moderate Cases Of Acne**

In case of Doxycycline treated group the arithmetical mean of number of pustules before treatment is 3.26 and 2.03 at the end of sixth week.

**Table 13: No. of pustules in each patient in group A of trial III**

S.No.	visit 0	visit 1	visit 2	visit 3	visit 4	visit 5	visit 6
1	2	2	2	2	2	2	3
2	3	4	3	1	2	2	4
3	4	3	2	2	3	0	0
4	3	3	2	3	1	2	2
5	4	3	2	3	2	2	1
6	2	4	3	1	2	2	1
7	4	2	3	2	3	0	2
8	3	3	2	2	2	3	3
9	4	3	3	2	2	2	2
10	2	2	3	3	2	3	2
11	3	1	3	3	3	2	2
12	4	3	3	3	3	3	3
13	3	3	2	1	2	0	2
14	4	1	3	3	3	2	3
15	4	4	1	2	2	1	2
16	3	2	2	1	3	2	3
17	4	3	3	2	4	3	0
18	4	3	3	1	3	4	2
19	4	2	3	2	2	0	1
20	3	2	2	2	1	2	2
21	4	4	2	1	1	1	3

22	3	3	3	4	2	1	4
23	4	3	2	3	1	2	4
24	3	2	1	2	2	3	3
25	2	2	3	3	1	2	2
26	3	3	2	2	2	2	1
27	4	2	2	1	1	2	1
28	2	1	3	2	0	1	2
29	2	3	3	1	2	1	1
30	4	4	3	2	1	1	0
Mean	3.26	2.66	2.46	2.06	2	1.76	2.03

In Clindamycin treated group the corresponding values are 3.36 and 1.36 before therapy and at the end of sixth week respectively

**Table 14: No. of pustules in each patient in group B of trial III**

S.No.	visit 0	visit 1	visit 2	visit 3	visit 4	visit 5	visit 6
1	3	2	1	2	1	3	0
2	4	3	2	1	2	2	2
3	3	3	3	0	0	0	3
4	4	3	1	1	2	2	2
5	4	2	1	2	1	1	3
6	3	1	3	2	1	1	0
7	4	3	3	2	2	2	3
8	4	3	1	3	1	0	0
9	4	2	2	3	2	2	2
10	3	2	2	3	1	2	1
11	4	3	1	1	2	0	0
12	3	2	2	3	1	1	3
13	4	2	3	2	0	1	1
14	3	3	0	1	2	0	1
15	4	3	2	2	1	1	3
16	2	2	3	1	3	1	2
17	4	2	3	2	1	2	1
18	3	3	0	2	2	3	1
19	4	3	3	1	2	2	2
20	2	3	2	2	3	1	1
21	3	2	3	1	2	0	0
22	4	2	2	2	2	1	0
23	3	3	2	3	2	0	1
24	2	3	3	3	1	2	2
25	2	4	3	1	2	3	1
26	4	2	3	2	2	4	1
27	4	2	1	2	3	0	2
28	3	3	2	1	1	2	1
29	4	2	3	1	0	1	0
30	3	3	2	1	0	0	2
Mean	3.36	2.53	2.06	1.76	1.5	1.33	1.36

**Results Of Trial IV**

**The Effect Of Drugs On Comedons In Moderate Cases Of Acne**

The group treated with oral Doxycycline along with topical Benzoyl peroxide the arithmetical mean of number of comedons was 4.66 on “0” visit that is before drug therapy and 1.86 at the end of sixth week.

**Table 15: No. of comedons in each patient in group A of trial IV**

S.No.	visit 0	visit 1	visit 2	visit 3	visit 4	visit 5	visit 6
1	4	2	5	3	1	2	1
2	5	5	4	0	1	3	4
3	5	4	3	2	3	4	3
4	5	3	1	0	3	0	1
5	5	5	4	3	2	2	3
6	5	4	3	2	3	1	4
7	4	1	4	4	4	3	0
8	5	4	2	5	3	1	4
9	5	3	3	3	2	3	3
10	4	3	4	0	3	1	2
11	5	4	1	3	2	2	1
12	4	4	4	3	0	1	3
13	4	4	3	2	3	1	1
14	4	1	2	3	2	1	2
15	4	4	3	3	0	0	1
16	5	4	1	2	2	1	2
17	5	4	3	3	3	3	0
18	5	3	2	1	1	2	3
19	5	3	1	0	2	1	0
20	4	4	3	3	1	1	1
21	5	4	1	0	3	4	3
22	5	4	1	3	1	3	0
23	5	4	3	3	0	0	3
24	5	5	2	4	1	3	1
25	5	5	0	3	3	2	3
26	4	4	3	0	1	0	1
27	5	4	4	3	3	1	3
28	5	3	2	2	2	3	2
29	4	5	4	2	3	0	1
30	5	3	3	1	2	1	0
Mean	4.66	3.66	2.63	2.2	2	1.66	1.86

In case of oral Clindamycin along with topical Benzoyl peroxide the values recorded are 4.7 before therapy and 0.96 at the end of sixth week.

**Table 16: No. of comedons in each patient in group B of trial IV**

S.No.	visit 0	visit 1	visit 2	visit 3	visit 4	visit 5	visit 6
1	5	3	0	3	1	1	2
2	5	2	2	2	1	0	0
3	5	3	4	1	0	2	1
4	4	3	3	2	1	0	0
5	5	4	4	3	0	1	0
6	4	3	3	3	4	0	1
7	4	2	2	2	0	1	1
8	4	3	3	1	1	2	1
9	4	3	3	2	0	3	1
10	5	2	2	0	0	1	3
11	5	4	3	3	1	1	1
12	5	3	2	2	0	1	2
13	5	4	3	2	0	3	1
14	4	3	3	2	1	2	0
15	5	2	2	3	1	1	0
16	5	3	2	0	1	0	0
17	5	3	1	3	0	1	1
18	5	2	2	2	1	1	0
19	5	3	3	1	1	0	1
20	4	2	3	0	2	1	0
21	4	3	2	2	1	1	1
22	5	5	3	1	1	0	1
23	4	2	1	2	2	0	1
24	5	3	4	3	1	1	1
25	5	3	3	1	3	0	1
26	5	4	4	2	2	0	2
27	5	4	3	0	0	2	1
28	5	4	4	3	1	1	1
29	5	3	2	2	0	1	1
30	5	4	4	3	0	0	3
Mean	4.7	3.06	2.66	1.86	0.9	0.93	0.96

**The Effect Of Drugs On Papules In Moderate Cases Of Acne**

In the group treated with oral Doxycycline along topical Benzoyl peroxide the arithmetical mean of papules in 30 patients was 3.43 before therapy and 1.7 at the end of sixth visit.

**Table 17: No. of papules in each patient in group A of trial IV**

S.No.	visit 0	visit 1	visit 2	visit 3	visit 4	visit 5	visit 6
1	2	2	1	1	2	3	2
2	3	2	2	2	3	2	1
3	4	3	1	1	2	0	3
4	3	1	1	2	1	0	2
5	4	3	2	3	1	2	0
6	4	2	3	3	2	2	3
7	3	3	2	1	2	0	0
8	4	2	3	2	3	1	3



9	4	1	3	1	0	2	2
10	3	1	3	2	3	2	3
11	4	2	3	3	1	3	1
12	4	3	3	0	1	2	2
13	2	4	2	1	3	1	2
14	3	3	1	2	2	1	0
15	4	2	1	3	1	2	1
16	3	1	1	2	3	1	2
17	4	3	2	3	2	0	2
18	4	2	0	1	2	2	3
19	3	1	4	3	3	1	2
20	4	2	2	3	2	1	2
21	4	3	1	3	2	3	3
22	3	3	2	2	2	1	2
23	4	2	1	1	1	3	3
24	2	3	2	1	2	2	2
25	3	4	1	0	1	3	1
26	4	3	1	1	1	0	2
27	3	2	2	2	2	1	1
28	4	1	2	3	0	3	0
29	3	2	2	1	1	2	0
30	4	3	3	2	1	1	1
Mean	3.43	2.3	1.9	1.83	1.73	1.56	1.7

The value for the other group treated with oral Clindamycin along with topical Benzoyl peroxide are 3.6 and 0.90 at the end of sixth week respectively.

**Table 18: No. of papules in each patient in group B of trial IV**

S.No.	visit 0	visit 1	visit 2	visit 3	visit 4	visit 5	visit 6
1	4	2	1	1	0	0	0
2	2	3	3	1	1	0	1
3	3	1	1	1	1	2	2
4	4	3	1	0	2	1	1
5	3	2	3	2	0	0	1
6	4	1	2	1	1	1	2
7	4	3	1	2	2	1	1
8	3	2	2	3	1	1	1
9	4	3	1	0	0	0	0
10	4	2	2	2	1	0	1
11	3	3	2	2	1	2	0
12	4	1	0	0	1	1	0
13	4	2	2	2	0	2	1
14	3	3	1	1	1	1	0
15	4	4	2	1	1	0	1
16	3	3	0	0	1	1	1
17	4	2	2	1	2	0	1
18	4	1	0	1	0	1	2
19	4	2	2	0	1	2	2
20	4	1	0	1	0	1	1
21	4	3	0	2	0	2	1

22	4	1	3	0	1	0	0
23	4	3	1	0	1	1	1
24	4	1	3	1	1	1	1
25	4	1	2	1	1	1	0
26	2	2	0	0	1	2	1
27	3	1	2	1	2	1	2
28	4	3	1	2	0	1	2
29	3	1	2	2	1	0	0
30	4	3	1	0	1	1	0
Mean	3.6	2.1	1.43	1.03	0.86	0.9	0.9

**The Effect Of Drugs On Pustules In Moderate Cases Of Acne**

The arithmetical mean of the number of pustules in the group treated with oral Doxycycline along with topical Benzoyl peroxide is seen as 3.3 before therapy and 1.06 at the end of sixth week.

**Table 19: No. of pustules in each patient in group A of trial IV**

S.No.	visit 0	visit 1	visit 2	visit 3	visit 4	visit 5	visit 6
1	4	1	2	1	1	0	0
2	4	2	3	0	3	1	2
3	3	2	0	1	1	1	0
4	4	4	2	2	0	1	0
5	3	1	3	0	2	1	2
6	4	3	0	1	1	3	1
7	3	2	3	2	0	2	0
8	4	0	3	1	2	0	3
9	2	3	2	0	2	2	1
10	4	2	3	3	1	1	1
11	3	0	1	0	2	0	1
12	4	3	2	1	2	2	2
13	2	3	0	0	1	1	1
14	3	0	3	2	1	0	1
15	4	1	0	1	0	3	1
16	3	3	1	1	0	1	1
17	3	0	0	2	1	1	0
18	2	2	1	0	1	2	0
19	4	3	2	3	1	0	1
20	4	3	3	1	0	2	1
21	3	2	2	1	0	2	1
22	3	1	2	3	1	0	2
23	4	0	3	1	3	2	0
24	4	3	2	1	1	0	0
25	3	1	0	2	0	1	3
26	4	4	1	1	2	1	2
27	3	2	2	1	0	1	3
28	4	2	0	2	0	0	0
29	2	1	1	1	0	2	1
30	2	2	1	2	0	0	1
Mean	3.3	1.86	1.6	1.23	0.96	1.1	1.06

In the group treated with oral Clindamycin along with topical Benzoyl peroxide the values are

3.43 before therapy and 0.43 at the end of sixth week.

**Table 20: No. of pustules in each patient in group B of trial IV**

S.No.	visit 0	visit 1	visit 2	visit 3	visit 4	visit 5	visit 6
1	4	3	0	0	0	0	0
2	3	2	1	0	0	1	0
3	4	0	1	2	0	1	0
4	3	3	2	1	1	1	1
5	2	1	1	0	1	0	2
6	2	2	0	0	1	0	0
7	4	0	0	0	0	0	0
8	4	3	2	1	0	0	0
9	4	3	2	1	1	1	0
10	4	1	0	0	0	1	1
11	4	1	2	1	1	0	2
12	4	2	3	1	0	0	0
13	3	2	0	2	0	0	0
14	4	1	2	1	1	0	1
15	4	0	0	0	1	1	0
16	4	2	1	1	0	1	0
17	2	2	1	1	0	1	0
18	4	3	2	0	2	1	1
19	3	0	0	2	0	0	1
20	4	2	0	1	2	1	0
21	2	1	2	0	0	0	0
22	4	1	1	1	0	0	0
23	3	2	1	1	0	1	0
24	4	2	1	0	0	0	0
25	2	3	1	1	1	0	1
26	4	2	0	1	0	1	0
27	4	0	0	0	1	1	1
28	3	1	1	1	0	0	0
29	3	0	0	0	0	1	2
30	4	1	1	0	1	0	0
Mean	3.43	1.53	0.93	0.66	0.46	0.46	0.43

**DISCUSSION**

Clindamycin produces very good effect in acne vulgaris and this is discussed later. These effects are produced without significant adverse effects. In few cases reported as Nausea, Vomiting, Diarrhoea were clinically insignificant and they were self-limiting [7]. The patients revealed the occurrence of such effects only after questioning them specifically for such an effect. If Diarrhoea, Abdominal pain had been severe they would have definitely reported to the investigator but no one reported. And all of them continued to take the drug without stopping [8]. Here also it should be noted that if Nausea and Vomiting had been due to Pseudomembranous enterocolitis, the condition would have worsened with continuous intake. But the symptoms were self-limiting [9]. Only three cases of Dysentery were prescribed tablet Metronidazole by their own doctor. On analyzing the efficacy of oral Clindamycin, a low dose that is 50 mg administered daily for four weeks has definitely produced better results than Doxycycline administered as a single daily dose for 4 weeks. There is significant reduction in the number of Comedons and papules in mild cases of acne vulgaris who have received only oral Clindamycin when compared to other group who have received only oral Doxycycline [10]. This is evident both in the clinical data which has been presented under the results column and also has been found to be statistically significant. In moderate cases, also the significant improvement is seen in the group which is treated with oral Clindamycin. This

is reflected as reduction in the number of Comedons, papules and pustules in the Clindamycin treated group, when compared to the other group which is Doxycycline treated control group [11]. The role of Propionibacterium acne in pathogenesis of acne has already been discussed. The anti microbials, Cap. Doxycycline and Cap. Clindamycin act in acne vulgaris by their effect on the Propionibacterium acne [12].

These antibiotics decrease the population of Propionibacterium acne which in turn leads to the inhibition of the bacterial lipases and this is followed by a decrease in concentration of free fatty acids.

This produces less tissue inflammation and acne. Since topically applied drugs are widely used in therapy of acne, in the trial groups in which the oral drug therapy was combined with topical Benzoyl peroxide and the outcome was analyzed [13]. Greater efficacy was obtained when oral Clindamycin was combined with topical Benzoyl peroxide. Doxycycline when used alone or in combination with Benzoyl peroxide has retained its efficacy, and the efficacy is greater when combined with topical Benzoyl peroxide [14]. Clindamycin either alone or in combination with topical Benzoyl peroxide 5% cream shows greater efficacy than Doxycycline either alone or in combination with topical Benzoyl peroxide 5% cream. The reason for lesser efficacy of Doxycycline could be due to development of resistance by Propionibacterium acne in some of the patients included in this trial [15].

### CONCLUSION

The study has proved that a low dose of 50 mg of oral Clindamycin administered once a day for four weeks produces good results in acne vulgaris. The good results are obtained without unwanted adverse reactions. For many infections 150 to 300 mg are given 3 – 4 times a day produces many adverse effects. In this trial the low dose of 50 mg used is not only highly effective, but also has not produced any significant adverse reactions. So far, the Clindamycin has only been used topically for acne vulgaris. This study encourages the use of low dose oral Clindamycin in acne vulgaris. Future trials using Clindamycin in combination with the other topical agents like Tretinoin and Adapalene which have different mechanism of actions can be tried. Tretinoin reverses abnormal keratinizing changes in acne vulgaris. Adapalene has got comedolytic property. This study proves the safety and efficacy of low dose of oral Clindamycin in acne vulgaris, and such low doses can also be tried for other infections where the causative organism responds to Clindamycin.

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