ORIGINAL ARTICLE

Comparison of Efficacy of Adapalene (0.1% Gel) Monotherapy Ve Adapalene (0.1%) Plus Benzyl Peroxide (2.5%) Combination Therapy for Treatment of Mild to Moderate Acne Vulgaris

MUHAMMAD KABIR[1], SARA SADIQ[2], ABEER RAZA[3], *SIDRAH KANWAL[4], TAMOOR TANVIR[5]*

ABSTRACT

Background: Acne is the most common disease of adult hood although no mortality is associated with it but it can result into drastic effects on one's life if not treated properly. Among much different treatment options Adapalene is a 3rd generation retinoid that work by comedo lytic anti-inflammatory decrease sebum production improve scaring and pigmentation having role both in acute and maintenance phases.

Aim: To compare the efficacy of adapalene (0.1% gel) monotherapy versus adapalene (0.1%) plus benzyl peroxide (2.5%) combination therapy for treatment of mild to moderate acne vulgaris.

Methods: It was a randomized controlled single blind study carried out at Dermatology OPD of NHM. One hundred and twenty eight patients were included in the study. Patients were randomly allocated in to two groups by lottery method. Sixty four patients in group-A will be treated with adapalene (0.1% gel) pea sized amount of gel applied every night after washing face with a mild soap and benzoyl peroxide (2.5% gel) pea sized amount of gel applied every morning after washing face with a mild soap daily for 12 weeks and, 64 patients of group-B will be treated with adapalene (0.1% gel) pea sized amount of gel applied every night after washing face with a mild soap. Patients will be followed up on every 4th week and any side effect will be noted.

Results: Of 128 patients, 60% were females and 40% were males. Mean patient age was25.11±3.116 years. Mean weight of patients was 58.36±5.047 kg. Effectiveness of those in group-A (combined therapy) was found to be 85.6% and those who were in group-B (monotherapy) showed 83.3% effective response. The effectiveness of both groups was compared by using chi square test and shows p value was found to be 0.588.

Conclusion:-Comparison of efficacy of adapalene (0.1% gel) monotherapy versus adapalene (0.1%) plus benzyl peroxide (2.5%) combination therapy for treatment of mild to moderate acne vulgaris showed that there is no significant difference in both groups

Keywords: Acne vulgaris, adapalene, benzoyl peroxide.

INTRODUCTION

Acne is a chronic inflammatory disease of pilosebaceous units. It is characterized by seborrhea, the formation of open and closed comedones, eryhtematous papules and pustules and in more severe cases nodules, deep pustules and pseudocyst[1]. It is the most common dermatological disorder affecting approximately 85% of individuals between 12 and 24 year of age[2].There is no mortality associated with this disease but often there is significant psychological morbidity. Propionibacterium acnes is now believed to contribute to inflammatory stages of the condition.

Treatment of acne depends on the type and severity of disease and includes topical and oral medications. Topical compounds are retinoids, benzoyl peroxide and antibiotics while antibiotics, isotretinoin and cyproterone acetate are commonly used oral compounds[3]. Effective treatment in acne is important to prevent scarring and psychological distresses.

Adapalene is a new synthetic, third-generation topical retinoid derived from naphthoic acid. The chemical name of adapalene is 6-[3-(1-adamynlye)-4 methonyphenyl]-2-naptholic acid. It is a white to off white powder which is tetrahedral form soluble in ethanol and insoluble in water. Adaplene is a 3rdgeneration retinoid that work by comedolytic anti-inflammatory decrease sebum production improve scaring and pigmentation having role both in acute and maintenance phases[4].

Benzoyl peroxide is a highly lipoplytic oxidizing agent with bactericidal and keratolytic effects[5]and circumvents the problem of resistance[6]. In a study conducted by Keating GM success rates in the treatment of mild to moderate acne with adapalene 0.1% gel vsadapalene 0.1% gel plus benzoyl peroxide 2.5% gel were found to be 54% and 75% respectively[7].

MATERIALS AND METHODS

The present Randomized controlled single blind study was conducted in the Department of Dermatology, Nishtar Hospital, Multan from 1st July 2016 to 31st December 2016. A total of 120 patients with age ranging from 18-30 years, both male and female with disease duration of more than 6 monthswere included in the study. Pregnant (confirmed by urine pregnancy test) and lactating women (inquired on history) and those already taking anti-acne treatment within one month.

A specialized proforma was developed to record the findings. Patients meeting inclusion criteria and exclusion criteria were enrolled in this study from OPD of Department of Dermatology, Nishtar Hospital Multan. Prior permission was taken from institutional ethical committee. Informed consent was taken from each patient describing them objectives of this study, ensuring them confidentiality of the information and fact that there was no risk involved to the patient while taking part in this study. Patients were

[1]Multan Skin & Hair Revival Clinic, Multan,
[2]WMO, DHQ Lodhran,
[3]MO, MINAR Cancer Hospital, Multan,
[4]Demonstrator, Shalimar Medical and Dental College, Lahore,
[5]MO Govt Hospital, Yakki Gate, Lahore
Correspondence to Dr. Muhammad Kabir
Email: shaukat372000@gmail.com *Cell: 0333-7736211*

randomly allocated in to two groups by lottery method. Sixty four patients in group-B were treated with adapalene (0.1% gel) pea sized amount of gel applied every night after washing face with a mild soap and 64 patients group-A were treated with adapalene (0.1% gel) pea sized amount of gel applied every night after washing face with a mild soap and benzoyl peroxide (2.5% gel) pea sized amount of gel applied every morning after washing face with a mild soap daily for 12 weeks Patients were followed up on every 4th week and any side effects were noted. On 12th week of treatment, effectiveness as defined in operational definition was assessed by measuring the global acne score in Dermatology out-patient department by the researcher under supervision of a consultant dermatologist having at least 5 years post fellowship experience. All data was entered in attached pro forma. Outcome variable i.e., efficacy were noted in the proforma.

All the data was entered and analyzed using SPSS version 20. Mean and standard deviation for the age, no. of lesions, BMI and duration of disease was calculated. Frequencies and percentage were calculated for the categorical variables like gender, disease severity, age groups, efficacy (Present/Absent) and Obesity (Obese/Non-obese). Efficacy was compared in both groups and chi-square test was applied for comparison of efficacy at level of significance of 0.05. Effect modifiers like age, gender, disease severity socioeconomic status, obesity, duration of disease were controlled by making stratified tables. Post stratification chi-square test was applied to see its effect on outcome. P value equal or less than 0.05 was considered as significant.

RESULTS

Of 128 patients, 76 (60%) were females and 52(40%) were males. Male to female ratio was 3:2 (Fig. 1). Mean patient age was 25.11±3.116 years. Details in this regard are given in Table 1. Mean weight of patients was 58.36±5.047kg (Table 2). Out of 128 patients, monotherapy was given to 64 patients and combination therapy was given to remaining 64 patients. Effectiveness of both drugs was recorded. Overall 108(84.4%) showed effective response and 20(15.6%) did not improve. Out of those who were given combination therapy, improvement was found in 55 (85.6%) and 9(14.4%) did not improve much as shown in Fig. 2. Those who are given monotherapy, 53(83.3%) showed effective response and 11(16.7%) did not show effective response as shown in Fig. 2. The effectiveness of both group was compared by applying chi square test and shows p value was found to be 0.681. Stratification was done with regards to age, weight and gender to see the effect of this on outcome (Fig.2,3,4,5).

Table 1: Age distribution

Valid	%	Valid%	Cumulative%
18 to 22	22.8	22.8	22.8
23 to 27	55.6	55.6	78.3
28 to 31	18.9	18.9	97.2
32 and above	2.8	2.8	100.0
Total	100.0	100.0	

Mean age (years) = 25.11 Standard Deviation = 3.116

Fig.1: Gender distribution

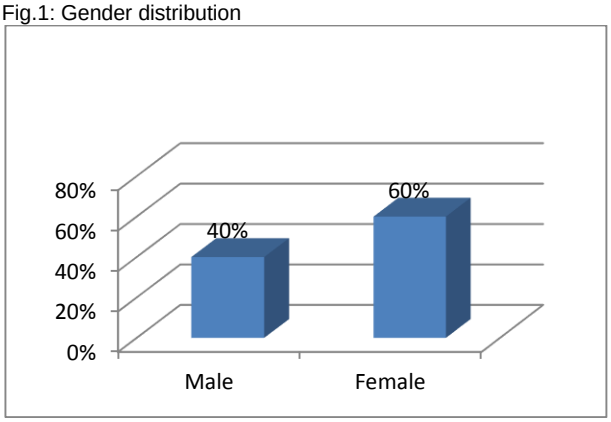

Fig. 2: Treatment response of two regimes with respect to age

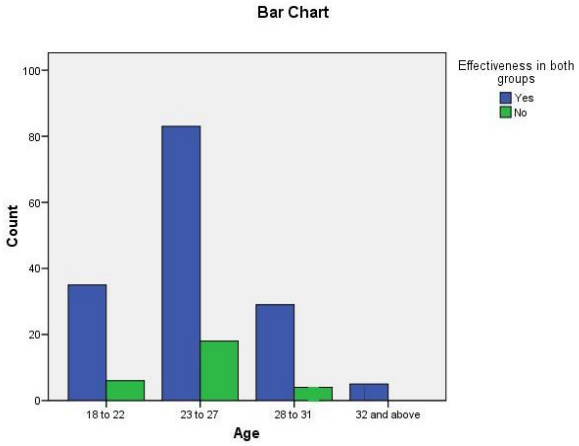

Fig. 3: Treatment response of both drugs with respect to weight of patients

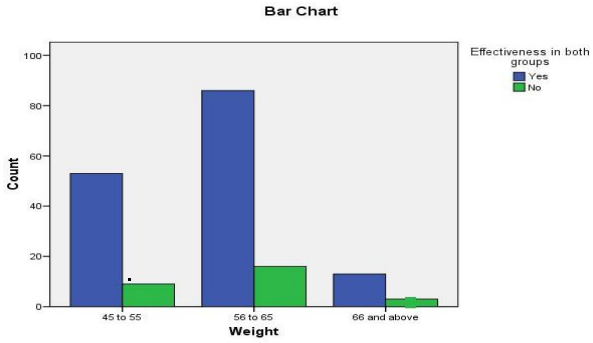

Fig. 4: Treatment response of both drugs with respect to gender

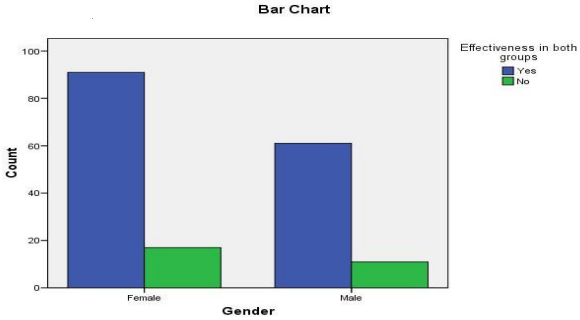

Table 2: Statistics of weight

Valid	%	Valid%	Cumulative%
45 to 55	34.1	34.1	34.1
56 to 65	56.7	56.7	90.9
66 and above	9.1	9.1	100.0
Total	100.0	100.0	

Mean weight (kg) = 58.36 Standard Deviation = 5.047

Table 3: Efficacy of medicine

Effective	Frequency	%
Combination therapy		
Yes	55	85.56
No	9	14.44
Total	64	100.00
Monotherapy		
Yes	53	83.33
No	11	16.67
Total	64	100.00

P value = 0.681

DISCUSSION

Acne a very common disease of adult hood as it mostly affects face thus can produce much impact on individual's psycho-emotional health. Moderate to severe acne is characterized by the presence of redness, inflammation, pustules, nodule, cysts and ultimately scar formation.

Oral isotretinoin (13-*cis* retinoic acid) is the treatment of choice in patients having moderate to severe acne. As multiple factors are involved in the pathogenesis of acne, oral isotretinoin produces its effect on most of them that is; it produces considerable reduction in sebum production, effects comedogenesis, decreases both surface and ductal *P. acnes* and also possess anti-inflammatory property. Furthermore it is distinct from other acne medications in its property that it can induce long-term suppression of activity of sebaceous glands. Though oral isotretinoin is extremely effective drug for acne treatment there are many side effects (such as cheilitis, xerosis, headache, hyperlipidemia, alopecia and fatigue) related to it and these are mostly dose-dependent. It is shown that these occur more frequently in those patients receiving high dose of drug. The standard dosage of isotretinoin is between 0.5 - 2.0 mg/kg/day given for at least 3 to 4 months. Different studies have been performed regarding the efficacy of low dose isotretinoin. So less toxic drugs are preferred over isotretinoin in patients with mild to moderate disease which we used in our study.

A study conducted compared effectiveness of monotherapy with adapalene and combination of adapalene with benzoyl peroxide in the treatment of acne concluded that there was no noteworthy difference in efficacy scores between the two groups. Patient satisfaction was greatest in the monotherapy regimen group and those receiving combination therapy were the least satisfied in the study. On the basis of satisfaction scores and presence of adverse events, the investigators concluded that the monotherapy group was the recommended regimen[7].

Another study conducted in 2014 studied the results that monotherapy with adapalene was effective and acceptable[8].

My study compared the combination of Adapalene and Benzoyl peroxide with monotherapy of Adapalene in acne patients. On the basis of history and clinical examination disease is diagnosed and patients are classified as having moderate to severe disease by using global acne grading system and those having 19 to 38 score were included in study. It was seen those who received conventional dose showed 85.6% response and those who were given low dose isotretinoin showed 83.3% response. The effectiveness of both groups was compared use chi square test and p-value was found to be 0.588 showing that there is no significant difference in the efficacy of both groups.

I am hopeful that my study and its findings will prompt a number of other studies on a larger scale to further explore the efficacy of use of less toxic drugs like adapalene and benzoyl peroxide in the treatment of acne and thus opt for the better treatment modality which will be of further help for treatment and management protocol.

CONCLUSION

Comparison between the effectiveness of adapalene (0.1% gel) monotherapy versus adapalene (0.1%) plus benzyl peroxide (2.5%) combination therapy for treatment of mild to moderate acne vulgaris showed that results in both groups are comparable and thus monotherapy can be opted as a better treatment modality as this regime makes the treatment more acceptable, because of lower incidence of dose related side effects, and lower the cost than the combination therapy.

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