The effect of medical education and counselling on treatment adherence and disease severity in patients with acne vulgaris: a non-randomised interventional study

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ABSTRACT

Introduction: Acne vulgaris (AV) is a common inflammatory skin disease affecting adolescents and young adults. It affects one's self-esteem and social relationship. In addition, poor adherence to treatment can cause poor treatment response and disease recurrence. This study aims to determine the effectiveness of medical education and counselling on treatment adherence and disease severity.

Methods: This is a non-randomised interventional study with age- and treatment- matched control conducted in a tertiary dermatology clinic from July 2021 to June 2022. Patients in the intervention group received a 10 min video presentation on acne, followed by treatment counselling. The adherence rate was determined objectively (pill counting and tube weighing) and subjectively (ECOB questionnaire). The disease severity was assessed using the Comprehensive Acne Severity Scale (CASS) and Global Acne Grading System (GAGS).

Results: A total of 100 patients completed the 12-week study. With intervention, patients have better adherence to topical medication (5% benzoyl peroxide gel: 71% vs 57.9%, p= 0.031; 0.05% tretinoin cream: 58.7% vs 45.4%, p= 0.044) at week 12. However, the intervention program did not improve adherence to oral medication. Overall, with intervention, a significantly higher percentage of improvement in disease severity was noted (47.3% vs. 39.1%, *p*=0.044). Non-adherence to treatment was attributed mostly to forgetfulness in 54% of the patients, followed by a busy lifestyle (41%) and little knowledge of acne (26%).

Conclusion: Patients have significantly better adherence to topical medication with education and counselling. Better adherence to treatment leads to more remarkable disease improvement.

KEYWORDS:
Acne, counselling, disease severity, education, treatment

INTRODUCTION

Acne vulgaris (AV) is a common inflammatory skin disease affecting adolescents and young adults. Acne lesions affect one's self-esteem and social relationship. As a result, those affected can experience difficulty at work and in social interaction.

Treatment for AV is widely available. The cause of failure to respond to therapy or relapse of disease is often due to poor adherence to treatment. Adherence to acne medication has been as low as 12.5% for the past 40 years.[1] One study reported poor adherence worldwide, with the worst rate in Europe (58%) than in Asia (48%) and America (43%).[2]

Multiple factors have been identified that can influence one's adherence to acne treatment. These include age, gender, education level, employment status, lack of acne knowledge, lack of satisfaction with treatment, treatment tolerability, frequency of follow-up visits and the doctor-patient relationship.[2-6]

Disease education and medication counselling are essential components during a daily clinic consultation. Nevertheless, many clinicians do not perform well in these two areas due to heavy clinic workloads and limited time. This study aims to determine the effectiveness of medical education and counselling on treatment adherence and disease severity. The secondary objective was to identify the risk factors affecting treatment adherence.

MATERIALS AND METHODS

Patient Population and Study Procedures

This interventional study was conducted at the dermatology clinic, Hospital Pulau Pinang, between July 2021 to June 2022. It was a 12-week study with three clinic visits (weeks 0, 6, and 12). Inclusion criteria were patients with AV who were 13 years age or older. Exclusion criteria were an acneiform eruption of any other causes, a pregnant or lactating patient, psychiatric disorders and cognitive impairment. Sample size calculation, together with consideration from drop-outs, we recruited 100 patients for this study. Informed written consent was obtained from the participants or parents of minors before recruitment. The age- and treatment-matched control group was selected at a 1:1 ratio by a doctor who was not involved in this study. Subjects were evaluated at weeks 0, 6 and 12.

Demography data was collected. An independent dermatologist assessed acne severity in weeks 0, 6 and 12 by using the Comprehensive Acne Severity Scale (CASS)[5] and Global Acne Grading System (GAGS).[8] Patients were prescribed with 5% benzoyl peroxide gel, 0.05% tretinoin cream, oral doxycycline or oral isotretinoin based on their acne severity. Throughout this study period, all the patients were allowed to use their own cleansers and moisturisers.

Medication adherence was assessed in weeks 0, 6 and 12 using the objective method (tube weighing and pill counting) and subjective method (ECOB questionnaire).[9] At week 12, patients must also answer a separate questionnaire containing reasons for non-adherence to treatment.

The intervention group was provided with a 10-min video presentation on AV, followed by individual treatment counselling by a pharmacist at week 0. The video answered the ten most frequently asked questions regarding acne. We adapted acne information from patient information leaflets developed by the British Association of Dermatologists.[10] During the counselling, the pharmacist would demonstrate the medication administration methods, explaining the possible side effects and their management. Patients were reassured of the importance of treatment adherence even though they noticed no immediate progress. In addition, an acne information leaflet was distributed to them to consolidate their understanding of acne.

This study was approved by the Ministry of Health Medical Research Ethics Committee and the National Medical Research Registry (NMRR-21-1487-60586). Also, permissions were obtained from the respective authors to use the questionnaires above.

Adherence Assessment
Topical treatment
The amount of topical treatment the patient should have used was determined by estimating the acne surface area using the patient's hand. One 'hand area' of the involved skin requires 0.5 finger-tip unit (FTU) or 0.25 g of ointment.[11] One FTU is the amount of ointment expressed from a tube with a 5 mm diameter nozzle, applied from the distal skin-crease to the tip of the index finger. The patient was taught how to use the FTUs to manage treatment applications. Patients were given an adequate supply of topical medicine during the visits at weeks 0 and 6. We weighed the remaining topical gel/cream at subsequent visits at weeks 6 and 12 to ascertain the amount used. The formula to calculate topical medication adherence (MED AD) is: The actual weight of the medication used/the expected weight × 100%.

Oral treatment
Patients were supplied with the exact number of tablets during the visits at weeks 0 and 6. We did pill counting at subsequent visits in weeks 6 and 12. The formula to calculate oral MED AD is: The number of pills taken by the patient/the number of pills the patient should have taken × 100%.

ECOB Questionnaire
ECOB is a simple, validated questionnaire developed by Pawin et al.[9] There are 2 sets of questionnaires (topical and oral therapy) with 4 questions each. Patients are classified as poor adherers if one of their answers differ from the expected answer.

Disease severity Assessment
CASS questionnaire
This validated acne grading system incorporates a grading scale and lesion counting over the face, chest and back.[7] It is simple to use in clinical practice and strongly correlates with the Leeds grading. An assessor stands 2.5 m from the patient to assess acne disease severity. Acne severity is classified into grades 0 to 5 (clear to very severe).

GAGS questionnaire
This numerical grading system measured the acne severity over six locations: the forehead, left cheek, right cheek, nose, chin and chest and back.[8] Each type of acne is given a score (the comedone is 1; the papule is 2; the pustule is 3; and the nodule is 4). In addition, each location is given a factor: the forehead, left cheek; and right cheek are assigned a factor of 2; the nose and chin a factor of 1; the chest and upper back a factor of 3. The total score is the sum of all six regional scores: 1-18 is a mild disease; 19-30 is moderate; 31-38 is severe; ≥ 39 is very severe.

The percentage of improvement in acne disease severity at week 12 is calculated as: The difference between GAGS scores in week 12 and week 0 / GAGS score in week 0 × 100%.

Study Size
Until now, there has been no previous similar AV study with the same scoring system as we were doing. However, Bostoen et al.[12] had shown psoriasis disease severity and quality of life (QOL) improved significantly three months after the intervention group of patients underwent an educational program.[12] AV and psoriasis are chronic visible skin diseases that can be debilitating and affect one's QOL. The severity of both the conditions can range from mild, moderate and severe. Treatment for both the disorders involves topical and systemic, which need proper education and counselling to ensure treatment efficacy and better disease control. Hence, based on this paper, we used a G power calculator to count our sample size.

G* Power calculation 3.1.9.7 found that 90 patients were needed for this study. There is an 80% probability that the investigation would detect a treatment difference at a two-sided 0.05 significance level if the mean difference between treatments is 2 and the standard deviation is 2. An additional 10% is added to include possible drop-out cases. Therefore, the total sample required is 100 patients.

STATISTICAL ANALYSIS PLAN
IBM SPSS version 26 was used for statistical analyses. Categorical data were expressed as frequencies and percentages and analysed using the Pearson Chi-square test. The normally distributed continuous variables were summarised in mean and standard deviation, while the non-normally distributed variables were expressed as median and interquartile range. These data were analysed using an independent T-test and Mann-Whitney test. A multiple

logistic regression test was used to determine the association of factors affecting the adherence rate. The significance level was set as *p*<0.05.

RESULTS

Demographics

A total of 108 patients were assessed for eligibility at the dermatology clinic. Three patients did not fulfil the criteria so finally 105 patients were recruited. The age- and treatment-matched control group was selected at a 1:1 ratio. Five patients dropped out (three from the intervention group and two from the control group) during the study, leaving 100 patients successfully completed the 12-week study and proceeded with data analysis. There are no statistically significant differences in the demography between the intervention and control group. In the intervention group, two subjects moved to other cities to further their studies, whereby another one subject defaulted follow-up due to logistic reason. In the control group, one patient moved to another city due to job relocation and another one patient developed kidney disease and was put on immunosuppressants.

The mean age was 22.6 years. The median age of acne onset was 16 years, while the disease duration was 4 years. More than 50% of the patients in both the groups have a positive family history of acne and normal body mass index (BMI).

According to CASS, half of the participants in the intervention group had moderate acne, followed by mild acne (15, 30%) and severe acne (10, 20%). In the control group, 21 participants (42%) had moderate acne, 18 (36%) had mild acne and 11 (22%) had severe acne. Based on GAGS, the mean severity of acne in the intervention group was 21.2 ± 6.31 and 20.9 ± 6.98 in the control group.

Adherence rate

Table I shows the adherence rate between intervention and control groups at week 12. Based on the objective measurement, subjects in the intervention group had a better adherence rate in using 5% benzoyl peroxide gel compared to their counterpart in week 6 (74.6% vs 63.8%; *p*=0.057) and week 12 (71.0% vs 57.9%; *p*=0.031). Participants on 0.05% tretinoin cream also showed a significantly higher adherence rate in the intervention group in week 6 (*p*=0.045) and week 12 (*p*=0.044) compared to the control group. Subjects in the intervention group who received oral antibiotics or oral isotretinoin showed a higher adherence rate than the control group, but the difference was not statistically significant.

Based on the subjective measurement by ECOB, with intervention, patients on topical treatment were better adherers than the control group at week 12 (*p*=0.022). Although subjects who received oral therapy in the intervention group also had a higher number of good adherers, they were not statistically significant.

Disease Severity

Figures 1 and 2 show the comparison of disease severity based on CASS and GAGS between intervention and control groups on weeks 0, 6 and 12.

Patients showed improvement in disease severity in both, intervention and control groups at weeks 6 and 12. However, the difference between the two groups was statistically not significant. Thus, the degree of improvement in disease severity over the past 12 weeks was calculated. Patients in the intervention group had significantly greater improvement than the control group (median percentage of improvement 47.3% vs 39.1%, *p*=0.044).

Reasons for Non-adherence

Overall, 15 participants did not miss their medication throughout the 12 weeks of the study. For the remaining 85 participants (Figure 3), forgetfulness and a busy lifestyle were the two most common reasons for non-adherence to treatment (54% and 41%, respectively). The third most typical reason for non-adherence was little knowledge about acne (26%). Ten participants (12%) reported having adverse effects from topical medication, which included skin burning, stinging, redness, and dryness.

Factors affecting Adherence

There is no significant association of adherence with gender, age of onset, educational level, marital status, family history of acne, smoking status, type of acne, disease severity, knowledge about acne and patients' satisfaction.

The multiple logistic regression test showed that only two factors significantly affected good adherence. First, patients in the intervention group have 3.5 odds of better adherence to topical medication than their counterparts (*p*=0.027). However, the intervention did not improve adherence to oral medication (*p*=0.480). Secondly, those who believed the prescribed medication was effective also had better compliance (OR 5.12, 95% CI 1.19-22.10, *p*=0.029).

DISCUSSION

Demographics: The mean age of our subjects was 22.6 years, similar to a study done in the United Kingdom.[13] Dreno B et al.[2] showed that 47% of Asians had acne onset at 16-20 years, comparable to ours, which had a median age of 16 years. Although AV is not an inheritable disease, it inclines to occur in families.[2,14,15] Those with first-degree relatives with acne were more prone to moderate to severe, earlier onset and truncal acne.[14-16] Our study showed similar results where more than two-thirds of our participants had first-degree relatives with acne and were in the moderate-severe group. More than half of our study population had normal BMI. This finding supported previous studies that revealed no relationship between BMI and acne severity.[14,15,17]

Adherence Rate

Table II summarises previous literature on acne medication adherence.

We did tube weighing and pill counting to objectively assess the patient's adherence. Our subjects in the intervention group performed significantly better in treatment adherence than their counterparts. Myhill et al.[13] mentioned patient education material helped increase treatment adherence compared to more clinic visits and combination topical drugs.

Table I: Adherence rate between intervention and control groups at week 12

	Overall adherence n=100	Intervention n=50	Control n=50	*p* value
a) Objective measure				
5% benzoyl peroxide gel, %, mean (SD),	64.5%	71.0 (28.05)	57.9 (31.48)	0.031*
0.05% tretinoin cream, %, mean (SD)	51.9%	58.7 (28.73)	45.4 (23.92)	0.044*
Oral antibiotic, %, Median (IQR)	94.3%	95.2 (7.14)	94.6 (11.90)	0.551**
Oral isotretinoin, %, mean (SD)	96.1%	96.3 (4.91)	95.9 (4.51)	0.856*
b) Subjective measure (ECOB)				
Topical treatment, n (%)				
Good	81.0%	45 (90.0)	36 (72.0)	0.022‡
Poor		5 (10.0)	14 (28.0)	
Oral treatment, n (%)				
Good	41.9%	17 (45.9)	14 (37.8)	0.480‡
Poor		20 (54.1)	23 (62.2)	

*Independent T-test; ** Mann Whitney U test; ‡ Pearson Chi-square test;
§Total patient on oral medication was 74 people (37 in intervention, 37 in control group)

Table II: Literature review on acne medication adherence

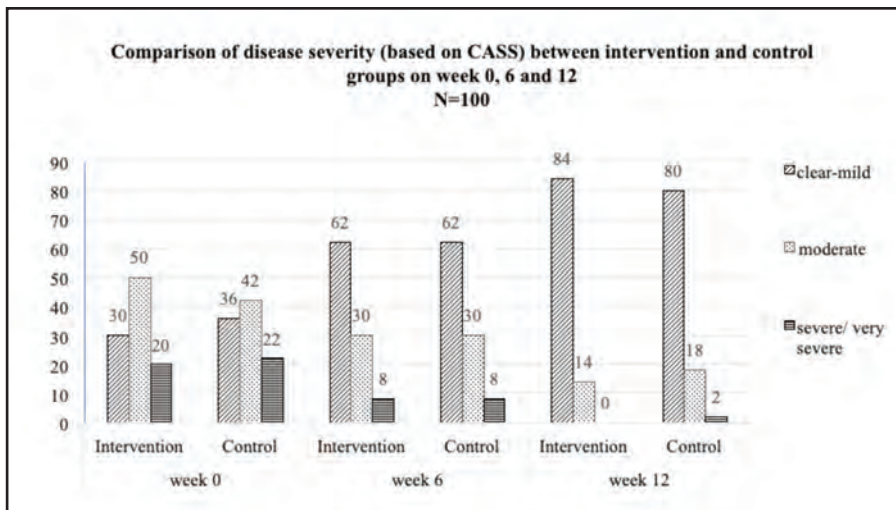| Study; year; country	Sample size	Measurement methods	Topical adherence rate	Oral adherence rate
Ling et al. (current study) prospective case-control study 2022 Malaysia	100	Pill count and tube weighing ECOB questionnaire	5% BPO gel: 64.5%; Tretinoin cream: 51.9% ECOB: 81.0%	Oral antibiotic: 94.3%; Oral Isotretinoin: 96.1% ECOB: 41.9%
Zaghloul et al.[3] Objective assessment of compliance with treatments in acne 2005 UK	403	Pill count and tube weighing	Topical and oral medication other than Isotretinoin: 35.2%	Isotretinoin: 71.4%
Dreno et al.[2] Large-scale worldwide observational study of adherence with acne therapy 2010 France	3339	ECOB questionnaire, self/dermatologist questionnaire	Topical only: 60% Combination oral and topical: 56%	Isotretinoin: 54% Combination oral and topical: 46%
Miyachi et al.[4] Acne management in Japan 2011 Japan	428	ECOB questionnaire, self/dermatologist questionnaire	Topical: 48% Combination topical: 51%	Oral: 7% Combination oral: 14%
Myhill et al.[11] Use of supplementary patient education material increases treatment adherence and satisfaction among acne patients receiving Adapalene 0.1% benzoyl peroxide 2.5% gel in primary care clinical a multicentre, randomised, controlled clinical study 2017 UK	97	Medication event monitoring system (MEMS) caps	Topical + supplementary education material group: 63.1% Topical + more visits: 48.2% Topical alone: 56.5%	-

The effect of medical education and counselling on treatment adherence and disease severity in patients with acne vulgaris

Fig. 1: Comparison of disease severity between intervention and control groups on weeks 0, 6 and 12 (based on CASS)
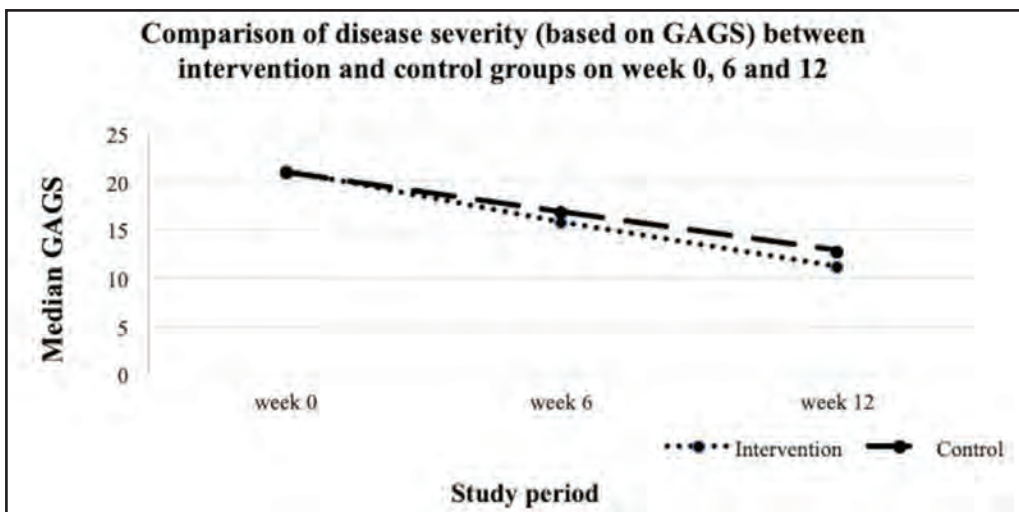

Fig. 2: Comparison of disease severity between intervention and control groups on weeks 0, 6 and 12 (based on GAGS)
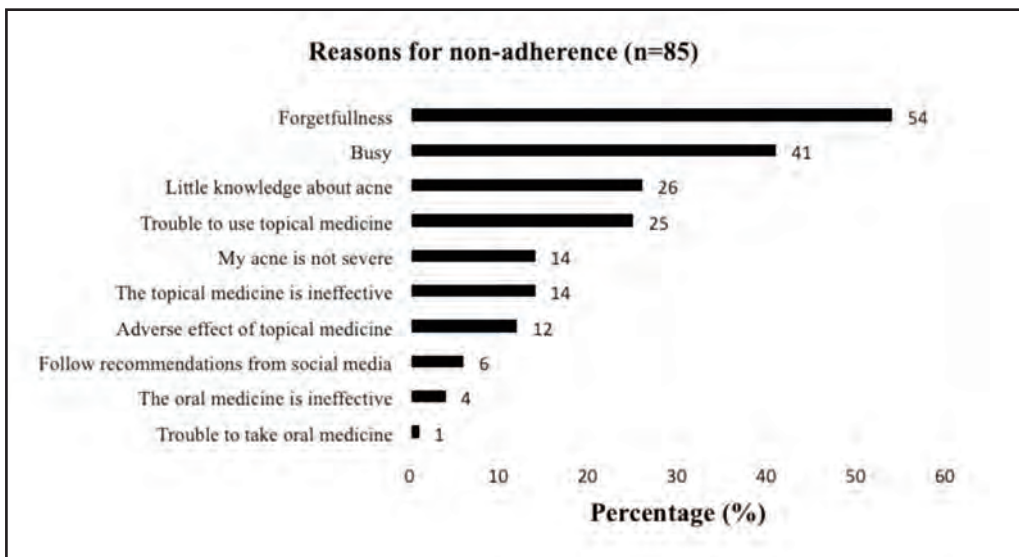

Fig. 3: Reasons for non-adherence

Using the pill counting method, both the intervention and control groups showed high adherence rates for oral antibiotic and isotretinoin throughout 12 weeks, ranging from 94.3-96.1% which was very much higher than the study by Zaghloul et al3 (adherence of isotretinoin: 71.4%). Although it was not mentioned the isotretinoin dosage used in Zaghloul's study, in our study, we used a lower dose of isotretinoin (10 mg or 20 mg once a day), which could lead to better tolerability compared to the standard recommendation dosages (0.5 mg/kg/day). Other reason for good oral adherence in our cohort could be the simplicity and convenience of taking oral medication once daily. Moreover, those on oral treatment generally had moderate-severe acne. Hence, they were more concerned about their self-images and were more disciplined when in treatment.

We also assessed the patient's adherence to acne treatment using the ECOB questionnaire. Contrasting to the objective results, our patients had poorer adherence to oral therapy than topical treatment in both the groups. This finding could be due to question 3 in the ECOB questionnaire (oral treatment). If subjects had forgotten to take these drugs at any time during treatment, they would be considered non-adherers. Most of our participants had missed medication at least 1 day throughout the 12-week study, and thus they were regarded as poor adherers.

On the other hand, the ECOB questionnaire (topical treatment) question 3 asks if the subject ever stopped taking topical drugs because they thought it would do more harm than good. Though our participants also did miss topical medication throughout the period, the reasons given were not due to the harmful effects of the topical drug. Hence, they were considered as good adherers.

Disease severity and Reasons for Non-adherence

Non-adherence to treatment is one of the primary roots of treatment failure, poor clinical outcomes and intensified healthcare utilisation. Most of our cohort reported forgetfulness and a busy lifestyle as the main reasons they did not adhere to their medications. Multiple ways to increase patient treatment adherence include reminder systems via automated text messaging, phone calls, phone applications or internet-based surveys, simplifying the treatment regimen, education and more frequent clinic visits.[18] We aim to increase our patients' knowledge of acne and its treatment, as poor knowledge is one of the most frequently reported reasons for poor treatment adherence.[2,4] Our intervention group had better adherence to topical treatment and showed more significant disease improvement at week 12 than their counterparts. Several studies in atopic eczema and psoriasis also reported that patient education effectively improves the disease severity.[19-22]

Patient education acts as an adjunct in the management of dermatological disorders. Adequate patient education helps patients to understand their disease and manage treatment expectations better, as well as empowers them to take accountability for their health.[23,24] Topical treatment is the cornerstone of dermatological conditions. It acts directly on the affected area with minimal systemic effects. However, the application can be messy and time-consuming. As a result, patients often consider topical treatments minor, less effective, and therefore do not use them regularly. Some even say they would rather receive an oral drug or injection than topical drugs.[25]

Factors Affecting Non-adherence

We only identified patients in the intervention group, and those who believed the prescribed medication was effective had better adherence than their counterparts. We did not find other factors such as gender, age of onset, educational level, marital status, family history of acne, smoking status, type of acne, disease severity, knowledge about acne and patients' satisfaction associated with adherence. Our findings contrast with other authors who found that those with more severe acne, good patient satisfaction and knowledge of acne treatment positively affect compliance.[2,4] A possible explanation is that our subjects' number was much smaller than theirs, thus unable to elicit the association.

Medical Education and Counselling in Acne

Previously, a structured teaching program conducted in a secondary school in India has improved adolescent students' knowledge of acne.[26] Burleigh et al.[27] also demonstrated that acne education enhances adolescents' quality of life. Given the substantial amount of time spent in a school setting, we can incorporate acne education programs in high school teaching modules to provide teenagers with scientific and independent information to help with this common condition and its psychological effects.

LIMITATION

As acne condition improves with treatment and time, the amount of topical medicine required would change over time. Hence, we might overestimate the patient's required amount and project a much lower adherence rate among those on topical therapy. In general, the 12-weeks study duration might be too short to accurately assess the treatment response. Future study with longer study duration would be more ideal in this context. Besides that, the sample size calculation should also include differences expected from ECOB questionnaire outcome.

CONCLUSION

Patients have better adherence to topical medicine with effective disease education and treatment counselling. However, it did not improve adherence to oral medication. Better medication adherence hastens the improvement in disease severity.

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