



Oral and written counseling is a useful instrument to improve short-term adherence to treatment in acne patients: a randomized controlled trial

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Key words: treatment, adherence, acne, counseling, randomized controlled trial

Citation: Navarrete-Dechent C, Curi-Tuma M, Nicklas C, Cárdenas C, Pérez-Cotapos ML, Salomone C. Oral and written counseling is a useful instrument to improve short-term adherence to treatment in acne patients: a randomized controlled trial. *Dermatol Pract Concept* 2015;5(4):4. doi: 10.5826/dpc.0504a04

Received: July 17, 2015; **Accepted:** September 23, 2015; **Published:** October 31, 2015

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Funding: None.

Competing interests: The authors have no conflicts of interest to disclose.

All authors have contributed significantly to this publication: the acquisition, analysis, and interpretation of data, drafting and revision of the article, and final approval for publication.

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ABSTRACT Background: Therapeutic success in acne patients not only depends on the appropriate selection of drugs but also on the patient's treatment adherence or compliance. Lack of adherence is an important problem both in general medicine and in dermatologic practice.

Objective: To evaluate the impact of oral and written counseling on treatment adherence among acne patients.

Patients and Methods: Eighty patients were randomized into two groups of 40 patients each. The intervention group received a patient information leaflet (apart from oral counseling), and instructions were reinforced by a telephone call within 15 days of treatment onset. The second group (control group) received treatment indications as usual (oral counseling in-office only). Both groups were followed up with a phone call, evaluating adherence to treatment according to self-reporting of patients at 30, 60, 90 days, and 6 months.

Results: Better adherence to treatment was observed in the intervention group. This difference was significant only within the first month of treatment (80% versus 62%, $p = 0.043$). The beneficial effect of written counseling plus a phone call decreased in subsequent months.

Conclusion: Written counseling significantly improves adherence within the first month of treatment. These results suggest that it is reasonable to spend time and resources in written counseling in order to optimize adherence to treatment.

Introduction

Acne has similar negative effects as chronic systemic diseases on mental, social health and on the patient's quality of life [1]. Therapeutic success not only depends on the appropriate selection of drugs, but also on the patient's treatment adherence or compliance [2]. Adherence is defined as the extent to which a patient's medication use and behavior matches or is consistent with the physician's prescriptions or whether the patient uses his/her treatment according to the assigned regimen [2]. Lack of adherence is an important problem both in general medicine and in dermatologic practice [3,4]. Despite this, few studies are available to evaluate a patient's adherence to treatments or prescriptions. We evaluated the impact of oral and written counseling on acne patients' adherence to treatment.

Methods

A randomized controlled trial was done between November 2008 and February 2009 in our department. We included 80 patients referred for evaluation and treatment of acne that agreed to participate in the study. They were randomized into two groups with a blind sequence of codes in a 1:1 proportion. The control group (CG) received oral counseling; education about pathophysiology of acne, treatment details and emphasis in treatment adherence. The intervention group (IG) received the same oral counseling, a patient information leaflet, and a phone call at day 15 after treatment initiation

to remind patients about treatment, give counseling, and give a chance to answer questions.

The evaluation of results was done with a telephone survey, without blinding, at 30, 60, 90 days, and 6 months after the first evaluation. This survey evaluated patient self-report of treatment adherence in four categories: (1) used every day, (2) used almost every day, (3) sometimes used, and (4) never used treatment. They were again rearranged into two categories: (a) good adherence: category 1 and (b) poor adherence: categories 2, 3 and 4. Intervention effect was evaluated as "rate of good-adherence" (treatment used every day). At the 6-month follow-up, an elective control was offered to all patients to evaluate efficacy of treatment. A blind evaluator did analysis by intention to treat (ITT). The SPSS (version 16.0.1) program and the Mann-Whitney U nonparametric test were used for statistical analysis. P-value < 0.05 was considered significant.

Results

Forty patients were included in CG, and 40 patients in the IG. Seventy-one patients completed the study and 9 patients were lost from follow-up: 5 from the IG and 4 from the CG. Groups had similar baseline characteristics (age, sex, severity and type of acne, site of involvement, type of treatment (topical vs systemic) and acne duration) (Table 1). Educational level was also similar in both groups. At 1-, 2-, 3- and 6-month follow-up an overall of 70%, 51%, 46% and 34%, respectively, of patients reported good adherence. IG ver-

TABLE 1. Clinical and demographic characteristics of the study population
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	Intervention group	Control group	p-value
Age (years)	17.2 (3.91)	18.23 (4.78)	p=0.756
Sex (male)	20 (50%)	25 (56%)	p=0.148
Acne severity:			p=0.107
Comedogenic	9 (22.5%)	4 (10%)	
Mild inflammatory	21 (52.5%)	18 (45%)	
Moderately inflammatory	8 (20%)	17 (42.5%)	
Severe inflammatory	2 (5%)	1 (2.5%)	
Site of involvement:			
Face	39 (97%)	38 (95%)	p=0.5
Thorax anterior	14 (35%)	15 (37%)	p=0.5
Back	22 (55%)	22 (55%)	p=0.589
Treatment modality:			
Topical treatment	38 (95%)	38 (95%)	p=0.692
Systemic treatment	15 (37%)	16 (40%)	p=0.5
Acne duration (years):	2.5 (1.93)	2.98 (2.9)	p=0.459

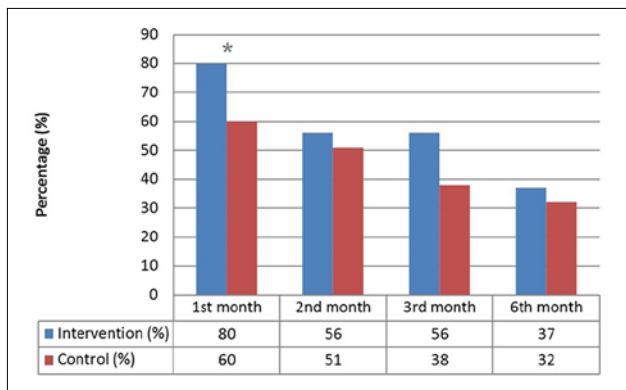


Figure 1. Reported good adherence percentages in the three months of follow-up (reported as everyday use of treatment); “*” indicates statistically significant differences ($p < 0.05$). [Copyright: ©2015 Navarrete-Dechent et al.]

the CG reported good adherence at 1-, 2-, 3- and 6-month follow-up was 80% versus 62% ($p=0.043$); 56% versus 51% ($p=0.41$); 56% versus 38% ($p=0.087$); and 37% versus 32% ($p=0.4$), respectively (Figure 1).

Good adherence was associated with use of oral treatments ($p=0.021$); attending regular follow up visits ($p=0.021$); increased perception of adverse events: mainly erythema ($p=0.046$); and a high perception of acne improvement ($p=0.064$). This high perception of acne improvement was associated to less “feelings of shame” ($p=0.001$); less use of coverage cosmetics and clothes ($p=0.046$); and less changes in social life ($p=0.03$).

Twenty-two out of the 80 patients (27.5%) attended the 6-month elective follow-up visit, with an overall rate of 73% clinical improvement, without significant differences between groups ($p=0.583$). Patients who reported “good adherence” at the first month had a tendency for a greater improvement of their acne: 86% compared with a 43% improvement in the group reporting “poor adherence” at the first month ($p=0.064$). The patients’ main reason for poor adherence was, according to them, “forgetfulness and desertion” (50%; Figure 2).

Discussion

Adherence to medical prescriptions is essential for a treatment’s success. Treatment adherence in acne patients has been reported as ranging from 12.5 to 65% [5]. Interventions to improve adherence to treatment in acne patients are not well defined [6,7,8]. In our study, treatment adherence was significantly higher in the first month in the IG compared to the CG (80% vs. 60% respectively), supporting our hypothesis that adherence could be improved with clinical interventions such as patient information leaflets and a phone counseling. Nevertheless, this effect seemed to decrease over time, with a 56% of good adherence at 3-month follow-up in the IG,

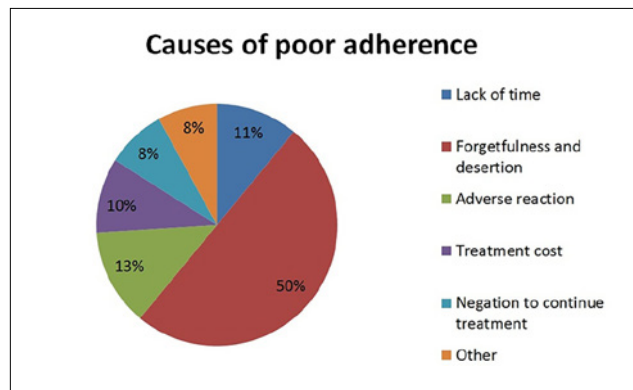


Figure 2. Patient self-reported causes of “poor of adherence.” [Copyright: ©2015 Navarrete-Dechent et al.]

similar to what is described in the literature with an overall 34% treatment adherence at 6-month follow-up, with no differences between IG and CG. However, these results should be interpreted with caution: There is a possibility of information bias, as the study outcome was not assessed blindly to the exposure.

Also, we observed a tendency to an improvement in adherence at the 2- and 3-month follow-up in the IG compared to the CG. Despite this, the results were not statistically significant.

Good adherence could help to obtain more effective treatments [9]. In our study, the patients reporting good adherence had better follow-up attendance, higher perception of improvement and a better quality of life. This data should be read carefully, as this is another potential source of bias: The evaluation of the therapeutic response included subjects that attended “electively” their follow-up visits and did not include all the subjects included in the study. It is probable that patients attending this “elective” visit were those who had greater improvement, tolerance, and probably better adherence than those who did not attend this final follow-up visit. In order to decrease the risk of bias, future investigations should include all patients in the study in the follow-up visit.

Another drawback of our study is that the evaluation of adherence (main outcome) was based exclusively on patients’ “self-report.” New ways of evaluating adherence to treatments include electronic monitors (automatic indicators located in pill boxes or cream dispensers with memory/records on how many times they were opened or “squeezed”). Nolan and Friedman elegantly described how patients may tell us how they used their medicines (“I used it religiously”); however, it is usually overstated, as comparing the patient’s diary with the electronic devices monitoring real adherence in research studies show [10]. Some examples include the Medication Event Monitoring System cap (MEMS, Aardex Group, Sion, Switzerland) that has the ability to record the

date and time of every opening/closing of the medication cap and that can be attached to any cream tube for studies [8].

We encourage clinicians to use written counseling during follow-up visits. "Phone counseling" is also an effective alternative for improving a patient's treatment adherence. These two interventions seem very reasonable, given the fact that "forgetfulness and desertion" are the main reasons for "poor adherence" as reported by our patients. As adherence improvement decreases over time, new strategies to maintain the patient's compliance are needed. We agree with Nolan and Friedman about the concept that adherence is the "fourth dimension" in dermatologic treatment and that improving it may help us to understand better treatment outcomes and make effective interventions to improve these outcomes [10].

Acknowledgements

We would like to thank Camila Downey, MD, for her assistance with English language and comments that greatly improved this manuscript.

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