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### Phonophoresis of Azelaic Acid Gel Versus Tazarotene Gel in Treatment of Acne Vulgaris: a single blind randomized controlled trial

Fonoforeza żelu kwasu azelainowego w porównaniu z żelem tazarotenowym w leczeniu trądziku pospolitego: pojedyncze ślepe randomizowane badanie kontrolowane

### Ibrahim Yousef Ibrahim Zidane<sup>1(A,B,C,D,E,F)</sup>, Wafaa Hussien Borhan<sup>2(A,C,D,E,F)</sup>, Adel Abd El Hamid Nosseir<sup>3(A,C,D,E,F)</sup>, Abeer Abd El –hakam Hodeib<sup>4(A,B,D,E,F)</sup>, Walid Ahmed Ibrahim Abouelnaga<sup>2(A,C,D,E,F)</sup>

<sup>1</sup>Department of Physical Therapy for Integumentary Disorders, Faculty of Physical Therapy, Kafrelsheikh University, Egypt <sup>2</sup>Department of Physical Therapy for Surgery, Faculty of Physical Therapy, Cairo University, Egypt <sup>3</sup>Faculty of Physical Therapy, 6 October University, Egypt <sup>4</sup>Department of Dermatology and Venereology, Faculty of Medicine, Tanta University, Egypt

### Abstract

Purpose. To compare between therapeutic efficacy of Azelaic acid 15% gel phonophoresis and Tazarotene 0.1% gel phonophoresis in treatment of acne vulgaris. Materials and methods. 80 patients with mild to moderate acne vulgaris with ages ranged from 18 to 25 years were randomly divided into four equal groups. Group (A): phonophoresis of Azelaic acid 15% gel. Group (B): phonophoresis of Tazarotene 0.1% gel. Group (C): (placebo ultrasound) topical Azelaic acid 15% gel without powered ultrasound. Group(D): (placebo ultrasound) topical Tazarotene 0.1% gel without powered ultrasound. Treatment administered (3 sessions / week) for 8 weeks. Acne count was determined at the beginning of treatment, after 4 weeks and after 8 weeks of treatment. Acnes count was measured using Digital Camera and the degree of improvement was determined using Investigator's Global Assessment. Results. Statistical analysis using ANOVA and repeated measures ANOVA showed that there was a significant decrease in acne count at post II of group A, B, C and D were 59.54, 78.31, 42.22 and 57.93% respectively. There was a significant difference in degree of improvement distribution between group A, B, C and D (p = 0.0001). group A (40%) moderate and (60%) marked, group B (15%) moderate and (85%) marked improvement, group C: (35%) mild, (60%) moderate and (55%) marked improvement, group D were (10%) mild, (35%) moderate and (55%) marked improvement. Conclusion. Phonophoresis of Tazarotene gel is more effective than Azelaic gel in reducing acnes count and improving cosmetic appearance of acne vulgaris patients.

### **Key words:**

Acne vulgaris, Phonophoresis, Azelaic acid gel, Tazarotene gel, Investigator's Global Assessment

### Streszczenie

Cel. Porównanie skuteczności terapeutycznej fonoforezy z użyciem żelu zawierającego kwas azelainowy 15% i fonoforezy z użyciem żelu zawierającego Tazaroten 0,1% w leczeniu trądziku pospolitego. Materiały i metody. 80 pacjentów z łagodnym do umiarkowanego tradzikiem pospolitym w wieku od 18 do 25 lat podzielono losowo na cztery równe grupy. Grupa (A): fonoforeza z użyciem żelu zawierającego kwas azelainowy 15%. Grupa (B): fonoforeza z użyciem żelu zawierającego Tazaroten 0,1%. Grupa (C): (USG placebo) miejscowo żel z kwasem azelainowym 15% bez ultradźwięków. Grupa (D): (USG placebo) miejscowo żel z Tazarotenem 0,1% bez ultradźwięków. Kurację stosowano (3 sesje/tydzień) przez 8 tygodni. Trądzik oceniono na początku leczenia, po 4 tygodniach i po 8 tygodniach leczenia. Trądzik oceniono za pomocą aparatu cyfrowego, a stopień poprawy określano za pomocą skali PGA. Wyniki. Analiza statystyczna przy użyciu ANOVA i ANOVA z powtarzanymi pomiarami wykazała, że w grupie A, B, C i D wystąpiła istotna redukcja trądziku po zastosowaniu kuracji w porównaniu z wynikiem przed leczeniem w grupie A, B, C i D (p < 0,001). Procentowa redukcja trądziku po kuracji w grupach A, B, C i D wynosiła odpowiednio 59,54, 78,31, 42,22 i 57,93%. Wystąpiła istotna różnica w rozkładzie stopnia poprawy między grupami A, B, C i D (p = 0,0001). Grupa A (40%) umiarkowana i (60%) wyraźna poprawa, grupa B (15%) umiarkowana i (85%) wyraźna poprawa, grupa C (35%) łagodna, (60%) umiarkowana i (5%) wyraźna poprawa, grupa D (10%) łagodna, (35%) umiarkowana i (55%) wyraźna poprawa. Wniosek. Fonoforeza z użyciem żelu zawierającego Tazaroten jest skuteczniejsza niż fonoforeza z użyciem żelu zawierającego kwas azelainowy w redukcji trądziku i poprawie wyglądu pacjentów z trądzikiem pospolitym.

### Słowa kluczowe

trądzik pospolity, fonoforeza, żel z kwasem azelainowym, żel z tazarotenem, skala PGA



### Introduction

Acne vulgaris is a disorder of the pilosebaceous follicles characterized by inflammatory lesions (nodules, pustules and papules) and non-inflammatory (closed and open comedones). Acne pathogenesis is a multiply of several factors: (i) Inflammation, (ii) bacterial colonization (iii) Excessive sebum production and (iv) Epidermal hyperproliferation with subsequent follicle plugging [1, 2].

Investigator's global assessment (IGA) is a qualitative measure used to evaluate the degrees of improvement in acne vulgaris. It has approximately six severity grades: grade 0 (Clear indicates non-inflammatory or no inflammatory acne lesions), grade 1 (Almost clear indicates rare noninflammatory acne lesions with no more than 1 papule/pustule), grade 2 (Mild indicates some non-inflammatory acne lesions, no more than a few papules/pustules, but no nodules), grade 3 (Moderate indicates up to many non-inflammatory acne lesions, may have some inflammatory lesions, but no more than 1 small nodule), grade 4 (Severe indicates many inflammatory and non-inflammatory acne lesions, and few cysts and nodules) and grade 5 (very severe indicates highly inflammatory acne lesions predimonate, variable number of comodones, many papules/pustules and many nodulyocystic lesions) [3].

The number of acnes was determined at the beginning of the treatment, after 4 weeks as (post I) and after 8 weeks of the treatment as (post II) by comparing patient photos before and after treatment by a global improvement scale: (Worse indicates an increment in the number of acnes by 10% or more, unchanged indicates a change in the number of acnes by (-9-9)%, mild improvement indicates a reduction in the number of acnes by (10-39)%, moderate improvement indicates a reduction in the number of acnes by (40-59)%, marked improvement indicates a reduction in the number of acnes by (60-89)% and clearance indicates a reduction in the number of acnes by 90% or more) [4].

Treatment of acne includes (systemic, topical and laser therapies). Topicals aim to normalize abnormal keratinization process, minimize bacterial colonization, decrease sebum production and calm inflammation. Generally, topicals fall into larger categories of retinoids, antibiotics (targeted effects against specific bacteria) and antimicrobials. Topical benzoyl peroxide is a mainstay of acne treatment with many therapeutic effects (keratolytic, antimicrobial and anti-inflammatory). If monotherapy by (BPO) is inadequate; it can be taken with local antibiotics or retinoids but it should be with close monitoring of patients for any adverse reactions or irritation [5].

Use of azelaic acid gel (or cream) and sodium sulfacetamide are common examples of antimicrobial drugs used for acne treatment but sodium sulfacetamide can provide additional anti-inflammatory properties. Azelaic acid is a convenient treatment option for acne vulgaris with no or minimal side effects. it is a dicarboxylic acid that can modify epidermal hyperproliferation in follicles, abnormal proliferation of propionibacterium acnes and inflammation [5, 6].

Tazarotene is an example of synthetic retinoids approved by Food and Drug Administartion for the treatment of acne vulgaris. It is a prodrug that is converted in the skin to tazarotenic acid (the biologically active form) which helps to normalize hyperkeratinization in the pilosebaceous follicles and changes in the microenvironment of the follicles to decrease the proliferation of propionibacterium acnes [5, 7].

Phonophoresis (PH) is a therapeutic method that uses ultrasound to improve percutaneous delivery of drugs and penetration of the topicals to the deep tissues. Delivering drugs using ultrasound is a well-tolerated painless technique that prevent systemic adverse effects. Therapeutic effects of topically applied medications depend on several factors such as amount, rate, potential drug toxicity and penetration depth. Anti-inflammatory medications, local anesthetics and counterirritants (like menthol can induce pain relief by stimulation of cutaneous sensory receptors and subsequent skin inflammation) can be used in phonophoresis. PH is a pain-free, well-tolerated effective method with few adverse effects and has been used in musculoskeletal and dermatologic diseases for many years. Despite numerous clinical studies of PH, questions regarding effectiveness and validity of treatment remain [8]. Silicone gel phonophoresis is a more effective method for post-burn hypertrophic scar management than Contractubex gel phonophoresis or corticosteroid phonophoresis [9].

The mechanism of PH in improving transdermal drug transport is described as following; ultrasound has 2 principal modes: continuous and pulsed modes. Continuous mode provides thermal effects, while pulsed mode provides mechanical stresses or effects such as (microstreaming, acoustic streaming, cavitation, increased number of pores and increased size of skin pores). Generally, these effects result in improving skin permeation via augmented mechanical stress and/or production of temporary or permenant cavities through keratinocytes and corneocytes. Also, thermal effects play an important role. Cavitation (production of small air bubbles by splitting of molecules within keratinocytes by the mechanical effects of ultrasonic waves) has a greater effect than transient vasodiltation and hyperthermia caused by the thermal effects of ultrasonic waves. Oscillation of these bubbles can enhance percutanous drug transfer via perturbing the molecules of lipid bilayer in the stratum corneum. Also, it can produce mechanical stresses in the walls of blood vessels with subsequent improvement of blood vessels permeability. Ultrasound also can alter the porosity of skin through creating more pores, widening skin pores, and decreasing the tortuous nature of pores [10]. So, the aim of this study was to compare between therapeutic efficacy of Azelaic acid 15% gel phonophoresis and Tazarotene 0.1% gel phonophoresis in treatment of acne vulgaris.

### **Material and Methods**

### Design of the study

The study was designed as a randomized, pre- post-test, controlled trial.

### **Participants**

Eighty patients with mild to moderate acne vulgaris were selected from outpatient dermatology clinics of Kafr-elsheikh University to participate in this study. They were enrolled and assessed for their eligibility to participate in this study. Their ages ranged from 18-25 years. Acnes count was measured using Digital Camera and the degree of improvement was de-



termined using Investigator's Global Assessment. Participants were excluded if they had skin malignancy, circulatory and sensory problems, diabetes mellitus, systemic diseases and dermatological diseases other than acne vulgaris. Also, Patients with less than 10 white head lesions, more than 50 inflammatory lesions and more than three nodules were excluded. Written informed consent was obtained from each participant. This study was performed according to the Statement of the Declaration of Helsinki.

### Randomization

A computer-generated randomized table was the method used to implement the randomization using the SPSS program (version 25 for Windows; SPSS Inc., Chicago, Illinois, USA). Each participant had an identification number. These numbers were assigned into four groups equal in number (n = 20). Sequentially numbered index cards were secured in opaque envelopes. A blinded researcher opened the sealed envelope and allocated the patients according to their groups (figure 1).



Figure 1. Flow chart of the study

### Intervention

Group (A): received phonophoresis of Azelaic acid gel 15%. Group (B) received phonophoresis of Tazarotene 0. 1% gel. Group (C) is ultrasound (placebo) group received topical Azelaic acid gel 15% without powered ultrasound. Group (D): is ultrasound (placebo) group received topical Tazarotene 0. 1% gel without powered ultrasound. All groups received the treatment three sessions per week for 8 weeks.

### Evaluation

### Photographic method:

• The patients were given 10 minutes to adapt to room conditions, photos were taken with the patient in a comfortable position. • The camera was applied vertical to the affected area. Room light was sufficient enough to take out clear photos.

• The distance between the patients and camera, magnification and illumination were fixed for all patients.

• Photographs were taken at the beginning of the treatment, after (4) weeks as (post I) and after (8) weeks of the treatment as (post II).

Investigator's Global Assessment (IGA):

• IGA is a qualitative six-point severity scale used to evaluate the grade of acne with grades ranged from (clearance to worst) [4].

• Acne counts were determined at the beginning of the treatment (pretreatment), after 4 weeks as (post I) and after 8 weeks of the treatment as (post II).



### Table 1. Shows the grades of the IGA [4]

Grade	Degree	Description				
0	Clear	No inflammatory or non-inflammatory lesions				
1	Almost clear	Rare noninflammatory lesions with no more than one papule/pustule				
2	Mild	Some non-inflammatory lesions, no more than a few papules/pustules, but no nodules				
3	Moderate	Up to many non-inflammatory lesions, may have some inflammatory lesions, but no more than one small nodule				
4	Severe	Many non-inflammatory and inflammatory lesions, and few nodules and cysts				
5	Very severe	Many non-inflammatory and/or inflammatory lesions with some or many nodular lesions				

• The comparison was done each time to the initial acnes count, and the degree of improvement was determined as shown below in table 2.

### Table 2. describes the degree of improvement of acne [4]

Description (change in acne counts)	Degree of improvement
Decreased by 90% or more	Clearance
Decreased by $(60 - 89)\%$	Marked
Decreased by $(40-59)\%$	Moderate
Decreased by $(10 - 39)\%$	Mild
Change in acnes counts = $(-9 - 9)\%$	Unchanged
Increased by 10% or more	Worse

### Treatment procedures

- Patients were asked to uncover the area of treatment only.
- Patients were placed in proper and comfortable position.
- Apply a conductive gel on the treated area.
- The ultrasonic transducer was applied perpendicular to the treated area.

• The device was switched on, and the parameters were set as follows:

- The patient received pulsed ultrasonic (50% duty cycle), intensity

1.5 W/cm<sup>2</sup> and frequency (3 MHZ) for 10 min.

- After the end of session, the device was turned off, and the treated area was checked.

- The patients were asked to note any erythema or discoloration, if marked or painful erythema is present, therapy was ceased until erythema relieves.

- Frequency of therapy was 3 sessions per week for a period of 8 weeks.

### Data analysis

Descriptive statistics and ANOVA test were conducted for comparison of subject characteristics between groups. Chi-squared test (Fisher exact test) was conducted for comparison of sex, affected area and degree of improvement between groups. Normal distribution of data was checked using the Shapiro-Wilk test. Levene's test for homogeneity of variances was conducted to test the homogeneity between groups. ANOVA with repeated measures was conducted for comparison between pre, post I and post II measurements of acne count in each group. Post-hoc tests using the Bonferroni test were carried out for subsequent multiple comparison. The level of significance for all statistical tests was set at p < 0.05. All statistical analysis was conducted through the statistical package for social studies (SPSS) version 25 for windows (IBM SPSS, Chicago, IL, USA).

### Results

### Subject characteristics

Table 3. showed the characteristics of participants of the group A, B, and D. There was no significant difference in age, sex and affected area distribution between four groups (p > 0.05).

	Group A (Mean ± SD)	Group B (Mean ± SD)	Group C (Mean ± SD)	Group D (Mean ± SD)	p-value	
Age [years]	$21\pm2.38$	$21.65\pm2.47$	$21.2\pm2.14$	$21.1\pm2.53$	0.83	
Sex						
Females	11 (55%)	8 (40%)	10 (50%)	9 (45%)	0.8	
Males	9 (45%)	12 (60%)	10 (50%)	11 (55%)	0.8	
Affected area						
Face	13 (65%)	14 (70%)	15 (75%)	12 (60%)		
Back	4 (20%)	2 (10%)	2 (10%)	4 (20%)	0.92	
Upper limb	3 (15%)	4 (20%)	3 (15%)	4 (20%)		

### Table 3. Basic characteristics of patients

SD – standard deviation; p-value – level of significance



### Effect of treatment on acne count

### Within group comparison

There was a significant decrease in acne count at post I compared with that pre treatment in the group A, B, C and D (p < 0.001). The percent of decrease in acne count at post I of group A, B, C and D were 34.17, 41.74, 22.67 and 34.35% respectively.

There was a significant decrease in acne count at post II compared with that pre treatment in the group A, B, C and D (p < 0.001). The percent of decrease in acne count at post II of group A, B, C and D were 59.54, 78.31, 42.22 and 57.93% respectively.

There was a significant decrease in acne count at post II compared with that at post I in the group A, B, C and D (p < 0.001). The percent of decrease in acne count at post II of group A, B, C and D were 38.54, 62.77, 22.29 and 35.91% respectively (table 4).

### Between groups comparison

The difference in acne count between four groups was no significant pre treatment and at post I (p > 0.05). There was a significant decrease in acne count of group B compared with that of group A, C and D at post II (p < 0.001) and a significant decrease in acne count of group A compared with that of group C (p = 0.003) while there was no significant difference between group A and D (p = 1). There was a significant decrease in acne count of group D compared with that of group C at post II (p = 0.03) (table 5).

### Degree of improvement

The degree of improvement distribution of the group A revealed that there were 8 (40%) moderate and 12 (60%) marked and that in group B were 3 (15%) moderate and 17 (85%) marked. The degree of improvement distribution of the group C revealed that there were 7 (35%) mild, 12 (60%) moderate and 1 (5%) marked and that in group D were 2 (10%) mild, 7 (35%) moderate and 11 (55%) marked. The difference in degree of improvement distribution between group A, B, C and D was a significant (p = 0.0001). There was a significant increase in marked degree in group B and in mild degree in group C (Table 6).

### Table 4. Mean acne count pre treatment, post I and post II of group A, B, C and D

Acne count	Pre treatment	Post I	Post II		P value	
	mean ± SD	mean ± SD	mean ± SD	Pre treatment vs Post I	Pre treatment vs Post II	Post I vs Post II
Group A	$23.85\pm5.47$	$15.7\pm4.3$	$9.65\pm2.58$	0.001	0.001	0.001
Group B	$24.2\pm3.62$	$14.1\pm3.07$	$5.25\pm2.3$	0.001	0.001	0.001
Group C	$22.5\pm5.72$	$17.4\pm4.9$	$13\pm3.37$	0.001	0.001	
Group D	$24.6\pm4.53$	$16.15\pm3.5$	$10.35\pm3.2$	0.001	0.001	
	P = 0.56	P = 0.08	P = 0.001	0.001	0.001	

SD – Standard deviation; p-value – level of significance

### Table 5. Comparison of acne count at post II between group A, B, C and D

	Acne count			
	MD (95% CI)	P-value		
Group A vs group B	4.4 (1.92:6.87)	0.001		
Group A vs group C	-3.35 (-5.82: -0.87)	0.003		
Group A vs group D	-0.7 (-3.17: 1.77)	1		
Group B vs group C	-7.75 (-10.22: 5.27)	0.001		
Group B vs group D	-5.1 (-7.57: -2.62)	0.001		
Group C vs group D	2.65 (0.17: 5.12)	0.03		

Mean difference; CI – Confidence interval; p-value – level of significance

### Table 6. Degree of improvement between group A, B, C and D

	Group A	Group E	3	Group C	Group D	χ2 value
Mild	0 (0%)	0 (0%)	7 (35%)	2 (10%)		
Moderate	8 (40%)	3 (15%)	12 (60%)	7 (35%)	33.18	0.0001
Marked	12 (60%)	17 (85%)	1 (5%)	11 (55%)		

 $\chi$ 2 – Fisher's Exact Test; p-value – level of significance



### Discussion

This study aimed to compare between therapeutic efficacy of Azelaic acid 15% gel phonophoresis and Tazarotene 0.1% gel phonophoresis in treatment of acne vulgaris. Concerning acne count, statistical analysis revealed a significant decrease in acne count at post I compared with that pre treatment in the four groups, also there was a significant decrease in acne count at post II compared with that pre treatment in the four groups. There was a significant decrease in acne count at post II compared with that at post I in the four groups. Comparing the results between the four tested groups revealed that the difference in acne count between four groups was no significant pre treatment and at post I, also it revealed that there was a significant decrease in acne count of group B compared with that of group A, C and D at post II and a significant decrease in acne count of group A compared with that of group C while there was no significant difference between group A and D (p = 1). Finally, there was a significant decrease in acne count of group D compared with that of group C at post II. Concerning the degree of improvement, statistical analysis revealed that the difference in degree of improvement distribution between the four groups was a significant and there was a significant increase in marked degree in group B and in mild degree in group C. The results of the current study showed that both phonophoresis and topical treatment were effective in acne treatment but phonophoresis was superior than topical treatment, also showed that both azelaic acid gel and tazarotene gel were effective in acne treatment but tazarotene was more effective in reducing acne count and improving cosmetic appearance in acne patients.

Results of our study concerning the effect of tazarotene in improving acne vulgaris lesions confirm the observations of: Ibrahim et al. [7] and Swaroop [11] and results concerning effect of phonophoresis in increasing transdermal drug delivery confirm the observations of Wahba [13]. Ibrahim et al., [7] carried out a study to compare the safety and efficacy of dapsone gel 7.5% in relation to tazarotene gel 0.1% in the treatment of acne vulgaris. Response to treatment with tazarotene on the left side among the studied acne patients show mild improvement, moderate improvement and good improvement occurs in 15.8%, 42.1% & 42.1% respectively. The results proved that tazarotene is effective method to control acne with minimal adverse effects [7]. Swaroop et al. [11] carried out a study to compare therapeutic efficacy of topical Adapalene and 0.1% Tazarotene gel in the treatment of mild to moderate acne lesions. they concluded that Tazarotene gel has a better anticomedogenic effect than Adapalene gel with better clinical outcomes. The efficacy of both the topical agents is similar for inflammatory lesions (papules and pustules) with few adverse effects of both retinoids [11]. Wahid and Kadry [12] carried out a randomized controlled single blinded study to evaluate the the-

rapeutic efficacy of Tretinoin gel phonophoresis versus its topical application in the treatment of planter warts. Main outcome measure: Warts diameter (by using a diameter caliper) measured at beginning of the treatment, after 6th and 12th session. With no dropout, they found that analysis of 22 patients indicated significant decrease in wart diameter in Group A and non-significant improvement in Group B, so they concluded that phonophoresis of Tretinoin gel might be effective in improving transdermal drug delivery and treatment of planter warts [12]. Wahba, [13] carried out a randomized single-blind controlled study to evaluate the effects of calcipotriol plus betamethasone phonophoresis in the treatment of plaque psoriasis. By the end of treatment, they found that there was a significant reduction in the skin thickness in the study group as compared with that of control group (P < 0.0001) and concluded that phonophoresis of calcipotriol plus betamethasone diproprionate is an effective treatment measure in improvement transdermal drug delivery and plaque psoriasis treatment [13].

The advantages of phonophoresis and encouraging results of our study provides a good evidence of phonophoresis for increasing transdermal drug delivery and efficacy of tazarotene acid 0.1% gel as an effective treatment option for mild to moderate acne lesions, and validates further studies to evaluate treatments for a longer period of follow-up and with a larger number of patients.

### Limitations

Although Phonophoresis Tazarotene acid gel is the most effective agent for acne vulgaris treatment, it has some limitations as it is very expensive; therefore, the findings of the study may be limited by cost-effectiveness from a health service perspective. In addition, the study lacked a follow-up of the acne vulgaris among the analysed groups for several months after a rehabilitation program to evaluate the long-lasting effect.

### Conclusion

Phonophoresis is an effective modality for increasing transdermal drug delivery and Tazarotene acid gel is more effective than Azelaic acid gel in the treatment of acne vulgaris in the form of reducing acne counts and improving cosmetic appearance. Phonophoresis of Tazarotene gel is more effective than Azelaic gel in reducing acnes count and improving cosmetic appearance of acne vulgaris patients.

Adres do korespondencji / Corresponding author

### Ibrahim Yousef Ibrahim Zidane

E-mail: Dribrahimzidane@gmail.com

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