BENHA MEDICAL JOURNAL bmj
Print ISSN 1110-208X
Online ISSN 2357-0016

Original article

Comparison of the Efficacy of Topical Tranexamic Acid and Oxymetazoline Following Q-Switched 1064 Nm Nd: YAG Laser for the Treatment of Post Acne Erythema: A Split-Face, Controlled Trial

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Received: 1 January 2024

Accepted: 31 March2024

Abstract

Background: Post acne erythema is a common complication of acne with no gold standard treatment**.** Unfortunately, complete clearance of acne erythema may not always be achieved, therefore it is a therapeutic challenge. **Aim**: To compare the efficacy of Q-switched 1064 nm Nd:YAG laser when combined with topical OXZ on the right half and topical TXA on the left half for PAE. **Methods**: A controlled trial was conducted with 30 patients having PAE recruited from the outpatient clinic of Dermatology, department of Benha University Hospitals. All patients were subjected to Q switched Nd:YAG laser followed by topical treatment using split face model: OXZ on the right half and TXA on the left one. This regimen was repeated three times at a 2-weeks interval. Outcomes were assessed by digital photography. **Results**: The count and the grade of PAE on the two sides of the face were significantly improved after the end of both treatments compared to the baseline. Pain, and erythema were the most frequently reported adverse effects. **Conclusion**: A new effective combination of Q-switched 1064 nm Nd:YAG laser with topical vasoconstrictors regimen either TXA or OXZ has a promising role in PAE treatment with fewer side effects for PAE.

Keywords: Post acne erythema; Oxymetazoline; Tranexamic acid; Nd: YAG laser.

Introduction

Acne vulgaris (AV) is a chronic dermatological disease whose patients frequently complain of upsetting long-lasting erythema after acne lesions have been improved by AV therapy[1,2]. This condition is defined as post acne erythema (PAE)[3]**.** Post acne erythema involves erythematous macules, and telangiectasia,

with absence of comedones, which is a common sequalae of AV[3]. Moreover, although PAE is common in AV patients, there is no definite gold standard treatment for it [4]. Persistent PAE is cosmetically unacceptable, and could lead to psychological distress, and lower quality of life[5]. Unfortunately, complete clearance of PAE may not always be achieved, therefore it is a therapeutic challenge[4].

Variable treatment methods have been used to treat long-lasting PAE such as topical treatment as retinoids, and vasoconstrictors as oxymetazoline(OXZ)[6]. Topical OXZ is an alpha 1A-adrenoceptor agonist that causes vasoconstriction of the cutaneous microvasculature, which is FDA approved as an effective topical treatment for rosacea patients suffering from facial erythema[5,7].

Tranexamic acid (TXA) is an antifibrinolytic agent that inhibits plasminogen activation into plasmin, thus inhibiting angiogenesis induced by plasmin. It improves erythema by inhibiting vascular endothelial growth factor and decreasing pro-inflammatory cytokines (TNF alpha and IL 6) [8]. The promising therapeutic effects, cost effectiveness, easy preparation and application with an accepted safety profile makes TXA a very good option for patients presenting with PAE[8].

Laser therapy has become accepted treatment regimen for inflammatory AV and PAE. The most frequently used lasers are diode, pulsed dye (PDL), Nd: YAG, Erbium, and fractional laser. Recently, 1064-nm Q-switched laser has become available as a successful treatment for inflammatory AV[2]. In previous studies, the efficacy of several modalities of combination therapy to target specific features of erythema was well established[1]. Thus, a combination therapeutic strategy of laser therapy with topical vasoconstrictors may have promising efficacy in treating PAE[9].

Aim of work: to compare the efficacy of Q-switched 1064 nm Nd:YAG laser on treatment of PAE when combined with topical OXZ on the right half of the face and topical TXA on the left one.

Patients and methods

Study type, setting and participants:

This study is a split-face, controlled trial. Thirty patients with PAE were recruited from the outpatient clinic of Dermatology, Venereology, and Andrology department of Benha University Hospitals. Inclusion criteria included participants aged more than or equal to 14 years having PAE, with any grade of acne lesions, and agreed to seek no other cosmetic procedures during the study. we excluded patients with other facial conditions that would interfere with PAE assessment, patients with hypersensitivity to OXZ or TXA, patients who received any other therapy for acne or PAE, for at least 3 months before the study, pregnant and lactating women. The study was approved by the local Ethics Committee of Benha Faculty of Medicine (MS 18/4/2022).

Methods

All patients were subjected to the following:

History taking: A purposely designed sheet was performed for all patients, including

personal history as age, sex, and occupation, history of acne as age of onset, course, and duration, medical history, systemic illness, drug intake e.g., systemic retinoids, chemical peeling, laser, and family history of AV or PAE.

Patient preparation: Patients with inflammatory AV received a 2-weeks course of systemic antibiotics (Doxycycline 100 or 200 mg capsules per day according to severity).

Laser treatment: Topical anesthetic was applied for 15 minutes prior to each session, then the face was cleansed. Erythema lesions on both halves were subjected to one pass of Q switched Nd:YAG laser (manufactured by WONTECH co. in USA) that was used under the following parameters :1064 nm wavelength, a 7 mm spot size of the zoom handpieces, acne toning mode, 2.5 j/cm2 fluence and 8 hz frequency. All patients completed three sessions at 2-week intervals [(6)].

Topical therapy: After receiving laser therapy, patients received topical treatment using split face model: topical OXZ 0.05% solution from the current marketed formulation Otrivin® (Novartis) was applied to the right side of each subject's face. On the other hand, 5 ml TXA topically that was formulated directly from injection TXA (500 mg/ml) (the current marketed formulation Kapron® (Amoun) 5 ml ampoules that contains 500 mg TXA[(6)] were applied to the left face side. Topical treatment was applied once immediately after each laser session.

Follow up: Outcomes were assessed by patients digital photographing at baseline and after the end of follow up period (using Samsung camera, 50 megapixel) and PAE assessment was done three times (at week 2, 4, and 6).

Assessments were done as follows:

Clinical assessment: Grading of acne lesions was done using the Indian classification that depends on lesion's quantity, form, and severity [(10)]. Grade (1) includes comedones, and papules, grade (2) comprises papules, comedones, pustules, grade (3) includes pustules, nodules, abscesses, and grade (4) includes cysts, abscesses, scarring. Also, PAE lesion count was assessed. severity grading of PAE was based on clinician erythema assessment scale (CEA) [(11)]. Grade (0) (clear face without erythema), grade (1) (slight erythema), grade (2) (mild redness), grade (3) (moderate or marked erythema), and grade (4) (severe or fiery redness). Patients also assessed treatment outcome using patient's self-assessment (PSA) as: very dissatisfied (no improvement), dissatisfied (mild improvement), satisfied (good improvement) and very satisfied (excellent improvement) after the end of all sessions[(12)]. While investigator global assessment (IGA) scale was performed by two blinded dermatologists at the completion of treatment and was graded as none (0%), mild (0%-25%), moderate (26%-50%), marked (51%-75%), and excellent improvement (76%-100%)[(13)]. Safety assessment was done by recording adverse events throughout and at the end of treatment as pain, erythema, edema, pruritus, and dryness. An informed consent was obtained from all patients involved in the study.

Statistical analysis:

The collected data was revised, coded, tabulated and introduced to a PC using IBM SPSS Statistics for Windows, Version 25.0. Armonk, NY: IBM Corp. released 2017. Kolmogorov-Smerinov test was performed to test data normality. Parametric numerical data was presented as mean, and standard deviation, non-parametric numerical data was represented as median and range, while frequency and percentage were used to present categorical data. A Repeated Measures ANOVA was used to assess the statistically significant difference in prognosis of PAE count before and throughout the entire treatment in each of the study group either using OXZ or TXA. A Cochran's Q test was used to assess the statistically significant difference in prognosis of PAE grade before and throughout the entire treatment in each of the study group either using OXZ or TXA. A ***p*** value is considered significant if ≤0.05 at 95% confidence interval.

The sample size was calculated using G power program. It was based on setting power at 80%, alpha error at 5% and assuming the medium effect size difference is 0.3 between TXA and OXZ for PAE treatment. Following these assumptions, a sample size of 30 patients was sought to be sufficient for achieving study objectives.

Results

The present study was conducted on 30 cases with PAE. Table 1presents the socio-demographic characteristics of the patients. Their mean age was 21.8±5.8 years. About two thirds of the patients were females (66.7%), and students (60%). None of them had systemic illness nor taking any drug.

It is indicated in Table 2 that mean duration of acne disease was 3.4± 1.8 years; with more than half of the cases had gradual onset (56.7%), most cases had progressive course (93.3%); 40 % had comedones and occasional papules, and 33.3% had papules, comedones and few pustules. Family history for acne was positive for only 8 patients. Regarding PAE, the mean count of PAE at the baseline on the right half of the face was 21.9±10.1 while on the left side was 25.1±13.2. Concerning the grading of the PAE, on the right side; more than half (56.7%) were severe (grade 4). While on the left half of the face, the highest proportion were suffering from severe PAE (40%).

Overall, the mean PAE lesion counts on the right half of the face decreased significantly from a baseline mean of 21.8±10.2 to 14.9±8.9 after 2 weeks of treatment, to 11.9±7.5 after the 4 weeks of treatment, and to 10±6.8 after 6 weeks of treatment (***p***<0.001). This corresponded to a total decrease of 54.1% of the PAE lesions after the treatment **(Figure 1).** While on the left half, a significant decrease after treatment versus baseline. Mean PAE count decreased from a baseline of 25.9±12.4 to 19.6±9.5 after 2 weeks of treatment, to 14.6±7.3 after 4 weeks, and to 11.1±4.4 after the 6 weeks of treatment (***p***<0.001). This corresponds to 57 % reduction in mean PAE count after the completion of the treatment as shown in **figure 2.**

Regarding the progression of the PAE grade, on the right half, almost clear or mild redness grades had significantly increased

from 23.3% to 80% after the end of the treatment. While the moderate or severe redness grades were significantly decreased from baseline percent of 76.7% to 20% at the end of the treatment (***p***<0.001) **(Table 3).** Also, on the left half, there was a significant difference in the proportion of PAE grades after the treatment versus baseline. Regarding the grades of clear or mild erythema they were significantly increased from about 37% at baseline to 80 % at the end of the treatment. While the grades of moderate or severe erythema were significantly decreased from about two thirds (63.3%) at the baseline to one quarter at the end of the treatment (20%) (***p***<0.001) **(Table 3).**

Concerning patient's self-assessment for the treatment outcome, on the right side of the face, more than half of the patient were very satisfied (56.7%) and nearly one quarter were satisfied. While regarding their satisfaction of the treatment over the left face side, 40% were satisfied and one third were very satisfied (33.3%). However, one fifth were dissatisfied (20%).

According to the investigator global assessment scale, **Figure 3** shows on the right half of the face, more than one third showed moderate improvement (36.7%), mild and excellent improvement were reported in nearly one quarter each (26.7%). While on the left half of the face, one third showed mild and moderate improvement (33.3% for each). No patients neither in the right half nor the left half showed no improvement.

The majority (93.3%) of the patients reported feeling pain after both treatment on the right and the left face. Erythema was reported in the majority after treatment on the right face (93.3%) and in about two thirds (66.7%) on the left half of the face. Dryness and scaling were reported on both sides of the face by only two patients.

Table 1: Demographic and clinical characteristics of the studied patients (n=30)

Socio-demographic and clinical characteristics			**Total n=30**	
Age (years)		**Mean ± SD**	**21.8 ± 5.8**	
Gender	**Male**	**N, (%)**	**10**	**33.3%**
	Female	**N, (%)**	**20**	**66.7%**
Occupation	**Student**	**N, (%)**	**18**	**60%**
	Housewife	**N, (%)**	**8**	**26.7%**
	Manual worker	**N, (%)**	**2**	**6.7%**
	Teacher	**N, (%)**	**2**	**6.7%**
Systemic illness	**yes**	**N, (%)**	**0**	**0%**
Drug intake	**yes**	**N, (%)**	**0**	**0%**

n= numbers; %= percentage; SD= standard deviation

Table 2: Clinical characteristics of acne and erythema in the studied patients(n=30)

Clinical characteristics of acne			**Total n=30**	
Acne duration (years)		**Mean ± SD**	**3.4 ± 1.8**	
Acne onset	Gradual	N, (%)	17	56.7%
	Acute	N, (%)	13	43.3%
Course of Acne	Stationary	N, (%)	2	6.7%
	Progressive	N, (%)	28	93.3%
Acne grade*	Grade 1: Comedones, papules.	N, (%)	12	40%
	Grade 2: Papules, comedones, pustules.	N, (%)	10	33.3%
	Grade 3: pustules, nodules, abscesses.	N, (%)	5	16.7%
	Grade 4: cysts, abscesses, scarring	N, (%)	3	10%
Family history of acne	Positive	N, (%)	8	26.7%
Clinical characteristics of PAE			**Right half**	**Left half**
Count	Mean ± SD		21.9±10.1	25.1±13.2
Grade**	Grade 0= No erythema	N, (%)	0(0)	2(6.7)
	Grade 1= slight erythema	N, (%)	6 (20)	2(6.7)
	Grade 2= Mild or definite redness	N, (%)	1(3.3)	7(23.3)
	Grade 3= Moderate or marked redness	N, (%)	6(20)	7(23.3)
	Grade 4=Severe or fiery redness	N, (%)	17(56.7)	12(40)

n= numbers; %= percentage; SD= standard deviation; * According to Indian classification; ** According to CEA

Table (3): the progression of post acne erythema on both halves of face of the studied patients during the treatment course (n=30)

Clinical characteristics of PAE			**Total (n=30)**				**Test**
			Baseline	**2 weeks**	**4 weeks**	**6 weeks**	***P*-value**
Grade (Right half)	Grade 1 &2 (Almost clear or mild redness)	N, (%)	7 (23.3)	19(63.3)	19(63.3)	24(80)	**<0.001***
	Grade 3& 4 (Moderate or severe redness)	N, (%)	23(76.7)	11(36.7)	11(36.7)	6(20)	
Grade (Left half)	Grade 1 &2 (Almost clear or mild redness)	N, (%)	11(36.7)	18(60)	23(76.7)	24(80)	**<0.001***
	Grade 3& 4 (Moderate or severe redness)	N, (%)	19(63.3)	12(40)	7(23.3)	6(20)	

n= numbers; %= percentage; SD= standard deviation
* Statistically significant at $P \leq 0.05$; Cochran's Q test were used

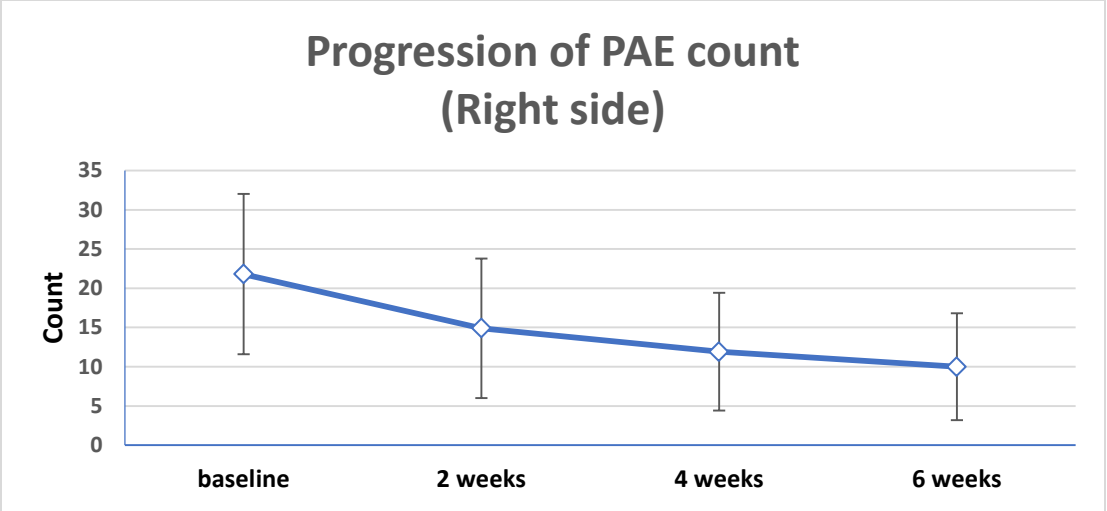

Figure (1). Progression of post acne erythema count in the right face through the treatment course by oxymetazoline.

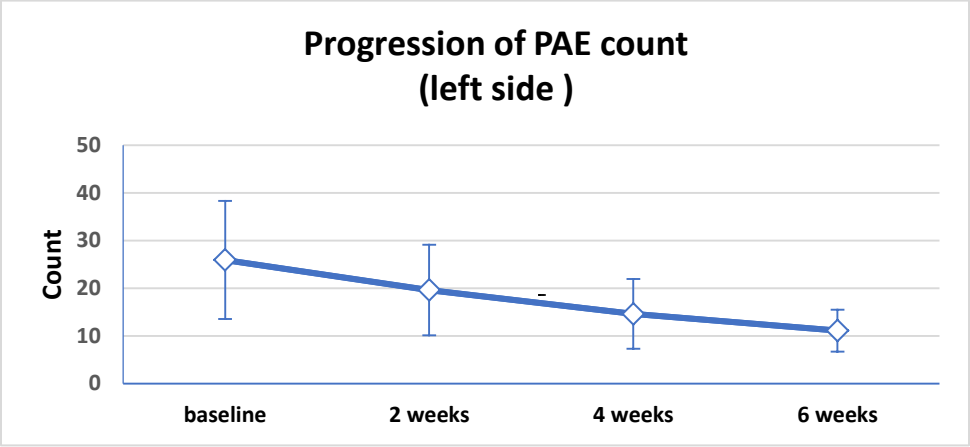

Figure (2). Progression of post acne erythema count in the left face through the treatment course by tranexamic acid.

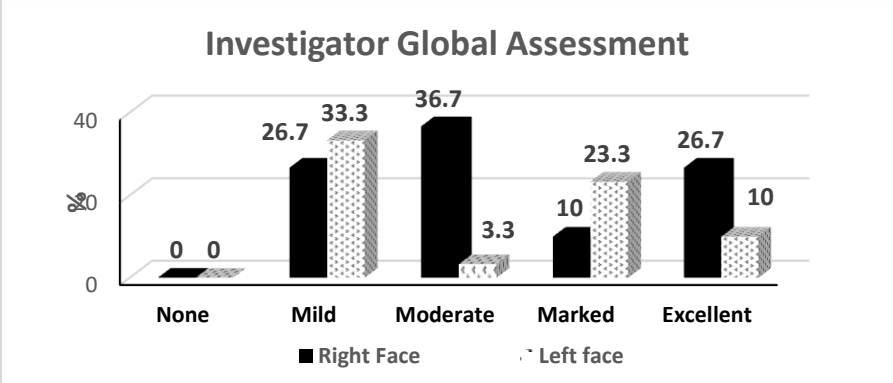

Figure (3). Investigator Global Assessment (IGA) scale of the treatment outcome

Discussion

Acne vulgaris can result in many consequences including PAE, which is esthetically unacceptable and without a gold standard therapy[14]. The prior randomized trials evaluated either the efficacy of 585 nm Q-switched Nd:YAG laser alone or used OXZ either alone or combined with other topical therapy or using TXA either through micro-needling or combined with other topicals[14]. Despite the previously studied modalities, it is still challenging [15,16]. To our knowledge, this is the first intervention study evaluating a promising regimen of PAE treatment using Q switched laser combined with either OXZ or TXA.

The present study revealed that there was a significant reduction in the PAE count with a total decrease of about 54% of the PAE lesions after the end of the sessions on the right half of the face and 57% on the left half. Moreover, both sides showed a significant improvement of the PAE grade.

These results were in agreement of the results of two previous studies that showed that both quasi-longed pulse and microsecond nm Nd:YAG laser resulted in a statistically significant reduction rate in the facial erythema[17,18]. In addition, another study compared 1064 nm Nd:YAG laser and IPL in AV treatment[20]. The patients treated with Nd:YAG showed 65.7% improvement of inflammation and erythema after three treatment sessions, 2-weeks interval. Similarly, previous studies showed a significant improvement of erythema by more than 50%, after three to four treatment sessions by the long-pulsed Nd:YAG laser of a 2-weeks interval [21,22]. Moreover, a study used 1,064-nm Nd:YAG laser in the treatment of facial acne and reported a 70.2% reduction of inflammatory lesions including erythema after three sessions, 4-weeks interval[23]. It is thought that therapeutic effect of 1064 nm Nd:YAG laser is based on damaging the dilated superficial vessel of acne inflammation and changing cytokine release, as TGF-βupregulation and IL-8 and TLR-2 downregulation, resulting in inflammatory acne lesions and erythema improvement[20,24].

According to a comprehensive literature review, OXZ was effective, safe, and well-tolerated therapy for rosacea associated with persistent facial erythema in a single or combined regimens[9]. In our study we used OXZ after Q switched laser on the right side of the face and revealed significant improvement of about 54% of the PAE lesions and reduction of the severity grading. When comparing our results with former studies using OXZ for PAE, a study revealed that there was a significant reduction (40%) in PAE lesion counts after a 12-weeks treatment duration and declared that OXZ was effective, well-tolerated, and safe for reducing PAE without a rebound effect[25].

We had higher rate of improvement because we used combined regimen of Nd: YAG laser followed by OXZ. Also, a previous study reported that topical OXZ was effective and reduced PAE significantly[3]. On comparing our results with previous

studies using TXA, our study reported that there was a significant reduction of PAE of the left side of the face (57%). A randomized, placebo-controlled, split-face study was performed on acne patients to assess the efficacy of 10% topical TXA in AV and PAE treatment. Their results showed 14 % reduction of inflammatory acne lesions and faster fading of the erythema lesions than in the placebo half[26]. The reduction in PAE was higher in our study than in their study because we used TXA after laser therapy while they used TXA serum only. Another study used 5% TXA in a daily treatment of PAE with promising results of PAE improvement within 6–8 weeks[8]. On the contrary, our results were shown to be lesser than the results of another study that used a topical triple therapy of TXA, OXZ, and brimonidine tartrate and showed about 65 % reduction in the PAE count[3]. The greater efficacy in their study may be explained by their usage of triple therapy for longer treatment duration of 3 months, while ours was dual therapy (Nd: YAG laser and TXA) for 1.5 months only. The efficacy of TXA in decreasing erythema is explained by depressing pro-inflammatory cytokines (TNFα and IL-6) and angiogenesis[27].

Concerning patient's self-assessment of the treatment outcome, our study showed that more than half of the patients were very satisfied with the treatment in the right half of the face, and nearly one quarter were satisfied. While regarding the left side of the face, one third were very satisfied and 40% were satisfied. Our results were also in agreement with previous study's results that used OXZ for PAE and showed that 50% of patients were very satisfied after 12 weeks of treatment of topical OXZ while 40% were only satisfied [3]. Also, it was reported that 98% of the subjects evaluated their overall improvement of PAE as good or excellent after using Q-switched Nd:YAG laser for 6 weeks in previous research[4].

In the present study, according to the investigator assessment scale, more than one quarter of the patients showed excellent improvement in the right half of the face. While in the left half of the face, about one quarter showed marked improvement. While excellent improvement was reported in 10% of the participants. On the contrary, another study used Q-switched Nd:YAG laser reported that 40% of subjects with severe erythema showed marked improvement in PAE[4]. Their study reported higher satisfaction level in their patients than ours as they included only patients with grade 1 and 2 of acne lesions while we included patients with all grades of acne. Also, they used 2 to 4 passes of laser, while we used only one pass with different parameters. Moreover, another study used topically applied OXZ for 3 months, and showed that 50% of the patients had excellent improvement, and about 40% had marked improvement[3]. Their higher improvement rates may be explained by using topical treatment for longer duration (3 months) while our study was only for one and half month and applying OXZ only once after each session of the 3 laser sessions.

The present study revealed that pain and erythema were the most commonly reported adverse effects on both sides of the face. These results were in agreement with preceding studies on PAE using Q-switched Nd:YAG laser or topical triple

combination[3,4]. Additionally, Nd:YAG laser was found to be safe, effective, and well-tolerated substitute with less side effects for erythema treatment[28,29] .

The novelty of our study adds to the existing literature a new treatment combination of Q-switched 1064 nm Nd:YAG laser therapy with topical vasoconstrictors regimen either TXA or OXZ with a promising role in treatment of PAE. However, the limitations of this study were short-term follow-up of patients and small sample size.

Conclusion

A new treatment combination of Q-switched 1064 nm Nd:YAG laser therapy with topical vasoconstrictors regimen either TXA or OXZ has a promising role with fewer side effects in PAE treatment. Further research with increased sample size is required to determine the long-term effects of Nd:YAG lasers. Also, further work up is required using a different regimen of topical treatment application that may be applied daily which may lead to better efficacy

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To cite this article: Manar M. Ellaban, Sherine Hosny. Comparison of the Efficacy of Topical Tranexamic Acid and Oxymetazoline Following Q-Switched 1064 Nm Nd: YAG Laser for the Treatment of Post Acne Erythema: A Split-Face, Controlled Trial. BMFJ 2024;41(1):211-221.