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ORIGINAL ARTICLE

Evaluation of Acitretin Versus Oral Isotretinoin in The Treatment of Common Warts

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ABSTRACT

Background: Warts are common benign tumors caused by human papillomavirus (HPV) infection, which is acquired from direct contact with an infected individual or from the environment. The aim of this work was to compare the efficacy and adverse effects of acitretin and oral isotretinoin in the treatment of common warts.

Methods: This study included 70 patients with multiple common warts who were selected from the Outpatient Clinics of Dermatology, Venereology and Andrology Department at Zagazig University Hospitals during the period from January 2020 to December 2020. A signed written consent was taken from each patient before being joined into the study that was approved by IRB at Faculty of Medicine, Zagazig University.

Results: Acitretin group showed complete response in 14 patients (50%), Isotretinoin group showed complete response 12 patients (42.9%), placebo group showed no response in all patients (0%). Adverse effects were more observed in those who received isotretinoin than who received oral acitretin. Recurrence was reported in one patient only of acitretin group and 2 patients of isotretinoin group after the 6-month follow-up period.

Conclusion: There was a highly significant variation in the treatment response between the treatment groups and the placebo group, while there was no significant variation between the two treatment groups although the complete response rate was slightly higher in the acitretin group than the isotretinoin group.

Key words: common warts, acitretin , isotretinoin , HPV, systemic retinoids.

INTRODUCTION

Warts are common benign tumors caused by human papillomavirus (HPV) infection, which is acquired from direct contact with an infected individual or from the environment. Warts are classified according to their appearance or site into different types like common warts, plane warts, plantar warts, and genital warts. Warts often cause significant discomfort and embarrassment **[1]**.

Common warts are hyperkeratotic, skin-colored papules sited mainly on the dorsa of the hands and feet. They are mainly caused by types 1, 2, and 4 HPV **[2]**. Most of the present treatment modalities of warts like chemical cautery, electrodessication, cryotherapy and laser therapy depend on the ablation of warts, however, they are usually cause pain, tissue destruction, scarring and high relapse rate. Moreover, these modalities are non-practical for patients presenting with a excessive number of warts, mainly on the palms, soles and periungual lesions **[3,4]**. Therefore, in recent years, the use of non-destructive methods such as contact sensitizers, intralesional immunotherapy, imiquimod, oral zinc sulfate and systemic retinoids has attracted much attention **[5,6]**.

Systemic retinoids, including isotretinoin and acitretin can be used as immunomodulators, anti-inflammatory agents and have an apoptotic effect..They have also been suggested to regulate differentiation and proliferation of keratinocytes, and inhibit the replication of HPV **[7,8]**.It has also been postulated that systemic retinoids may play a role in the management of HPV due to its anti-angiogenic properties through a reduction of production of vascular endothelial growth factor by keratinocytes**[9]**. Acitretin and isotretinoin have been suggested by some authors as promising, effective, well tolerated and non-invasive alternative therapies for the treatment of multiple and recalcitrant warts **[5,6,10]**.They have the advantage of acceptable cost, easy intake, extended remission time, and infrequent relapses, either

alone or in combination with other conventional therapies such as tretinoin**[11]** and intralesional immunotherapy like Candida antigen**[12]**.

METHODS

Patients: This study included 70 patients with multiple common warts who were selected from the Outpatient Clinics of Dermatology, Venereology and Andrology Department at Zagazig University Hospitals during the period from January 2020 to December 2020. A signed written consent was taken from each patient before being joined into the study that was approved by IRB at Faculty of Medicine, Zagazig University. The work has been carried out in accordance with the code of ethics of the world medical association (Decleration of Helsinki) for studies involving humans.

Inclusion Criteria: Adult patients of both sexes with multiple (5 or more) common warts of different sites, sizes and durations were involved in this study.

Exclusion criteria: Pregnant and lactating women, patients with abnormal liver function tests and abnormal lipid profile and patients who had received any other wart treatments in the last month before enrollment were excluded from the study. All patients were subjected to full history taking (Personal history: age, sex.

Present history: onset, course, duration of the disease. Past history: previous therapy.) Complete general examination. Dermatological examination to evaluate the different characteristics of the warts, including number, site and size at baseline and at each follow-up visit.

Methods: The patients were divided into 3 groups: Group I: Included 28 patients who received acitretin at a dose 0.5 mg/kg body weight/day until complete response or for a maximum of 3 months. **Group II**: Included 28 patients who received oral isotretinoin at a dose of 0.5 mg/kg/day until complete response or for a maximum of three months. In both groups: Lipid profile and liver function tests were evaluated before treatment and monthly after treatment for a whole duration of 3 months. **Group III**: Included 14 patients who received placebo capsule of the same color and size containing sugar powder.

Assessment of the clinical response

Response to treatment in the three groups was assessed by the reduction in size of warts and comparing images at baseline and every 2 weeks for 3 months. Adverse effects were also assessed at each treatment visit. The response was assessed as follows: Complete response: if there is complete clearance of the warts and return of normal skin markings. Partial response: if the warts have regressed in size by 50–99%.No response: 0-49% decrease in wart size**[13].**

Follow-up: Follow-up was done monthly for 6 months after stoppage of treatment to identify any relapse.

STATISTICAL ANALYSIS

Data were analyzed using IBM SPSS 23 for windows (SPSS Inc., Chicago, IL, USA) and NCSS 11 for windows (NCSS LCC., Kaysville, UT, USA). Categorical data were presented as number and percentages while quantitative data were expressed as mean ± standard deviation, and range. Chi square test (X^2) was used to analyze categorical variables. Quantitative data were tested for normality using Kolmogorov-Smirnov test, assuming normality at P>0.05, using ANOVA (F) test for comparing three means if normally distributed, or Kruskal-Wallis test if not normally distributed,

P value >0.05 is non-significant (NS)

P<0.05 is significant (S)

P≤0.001 is highly significant (HS)

RESULTS

The study involved 70 patients with multiple common warts (48 males and 22 females). They were divided to 3 groups: oral acitretin group, oral isotretinoin group, oral placebo group. All patients completed the study. There was no statistically significant association between age and therapeutic response among the studied groups, while a highly statistically significant association between sex and therapeutic response among the studied groups, where most of the patients (92.9%) in the acitretin group were males **Table (1)**. No statistically significant association between wart characteristics and therapeutic response was found between the studied groups and also there was no statistically significant association between previous therapy of warts and therapeutic response among the studied groups **Table (2)**. In acitretin group, complete response was achieved in 14 patients (50%) of the studied patients.In isotretinoin group, complete response was achieved in 12 patients (42.9%) of the studied patients. In the placebo group, complete response was not observed in any of the studied patients (0%). There was a highly statistically significant variation in the therapeutic response between the treatment groups and the placebo group, while there was no significant variation between the two treatment groups (P-value=0.76) **Table (3) Figure (5).**There was a highly statistically significant variation in the adverse effects between the placebo group and the treatment groups and also there was a highly statistically significant variation in the adverse effects between acitretin group and isotretinoin group (P value > 0.001). There was no significant variation in the recurrence rate between the two treatment groups **Table (4) Figure (6)**.

Table (1): Demographic characteristics among the studied groups

	Acitretin Group N=28	**Isotretinoin Group N=28**	**Placebo Group N=14**	**F test**	**P value**
	Mean ± SD	**Mean ± SD**	**Mean ± SD**		
Age **Mean ± SD Range**	**27.3 ± 7.61** **16 - 47**	**25.3 ± 7.67** **16 - 61**	**28.8 ± 9.17** **17 - 44**	**0.94**	**0.41** **NS**
	N (%)	**N (%)**	**N (%)**	**X^2**	
Sex **Male** **Female**	**26 (92.9%)** **2 (7.1%)**	**12 (42.9%)** **16 (57.1%)**	**10 (71.4%)** **4 (28.6%)**	**16.3**	**<0.001** **HS**

Table (2): Warts characteristics among the studied groups

	Acitretin Group N=28	**Isotretinoin Group N=28**	**Placebo Group N=14**	**KW Test**	**P value**
	Mean ± SD	**Mean ± SD**	**Mean ± SD**		
Disease duration (months) **Mean SD** **Median** **Range**	18.5 ± 13 12 1-120	13.9 ± 12.7 12 1-48	9.3 ± 7.22 6 1-60	4.04	0.13 NS
Number of warts **Mean SD** **Median** **Range**	14.2 ± 5.97 13 6-25	13.9 ± 6.97 14 5-34	10.7 ± 4.98 11 4-17	2.67	0.26 NS
	N (%)	**N (%)**	**N (%)**	**X^2**	**P**
Size **0.2 – 0.5 cm** **>0.5 – 2 cm**	14 (50%) 14 (50%)	20 (71.4%) 8 (28.6%)	10 (71.4%) 4 (28.6%)	3.31	0.19 NS
Previous treatment	18 (64.3%)	14 (50%)	10 (71.4%)	2.14	0.34 NS
Type of treatment Cryotherapy Salicylic acid Electrocautery Immunotherapy Combined therapy	 4 (22.2%) 6 (33.3%) 4 (22.2%) 2 (11.1%) 2 (11.1%)	 2 (14.3%) 4 (28.6%) 6 (42.9%) 0 (0.0%) 2 (14.3%)	 4 (40%) 2 (20%) 1 (10%) 1 (10%) 2 (20%)	6.51	0.59 NS
Site **Feet** **Hands** **Feet and hands**	 12 (42.9%) 10 (35.7%) 6 (21.4%)	 8 (28.6%) 14 (50%) 6 (21.4%)	 4 (28.6%) 8 (57.1%) 2 (14.3%)	2.41	0.66 NS

Table (3): Therapeutic response among the studied groups

	Acitretin Group N=28	**Isotretinoin Group N=28**	**Placebo Group N=14**	**X^2**	**P value**
	N (%)	**N (%)**	**N (%)**		
No response Partial response Complete response	4 (14.3%) 10 (35.7%) 14 (50%)	6 (21.4%) 10 (35.7%) 12 (42.9%)	14 (100%) 0 (0.0%) 0 (0.0%)	34.9	<0.001 **HS**

Table (4): Adverse effects and recurrence rate among the treatment groups

	Acitretin Group N=28	Isotretinoin Group N=28	Placebo Group N=14	X^2	P value
	N (%)	**N (%)**	**N (%)**		
Adverse effects	10 (35.7%)	28 (100%)	0 (0.0%)	36.5	<0.001 HS
Type of adverse effects					
Dryness of the lips	8 (28.6%)	28 (100%)	0 (0.0%)	52.4	<0.001 HS
Skin desquamation	2 (7.1%)	0 (0.0%)	0 (0.0%)		

	Acitretin Group N=14	**Isotretinoin Group N=12**	**X^2**	**P value**
	N (%)	**N (%)**		
No recurrence	13 (92.9%)	10 (83.3%)	Fisher	0.342 NS
Recurrence	1 (7.1%)	2 (16.7%)		

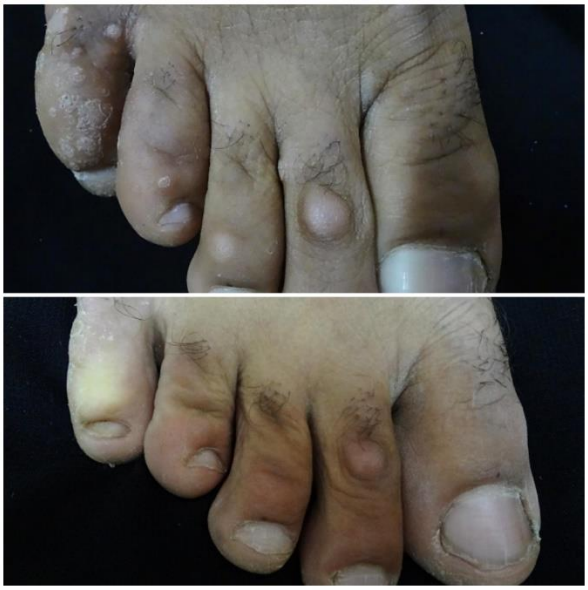

Figure (1): patient treated with acitretin for 3 months

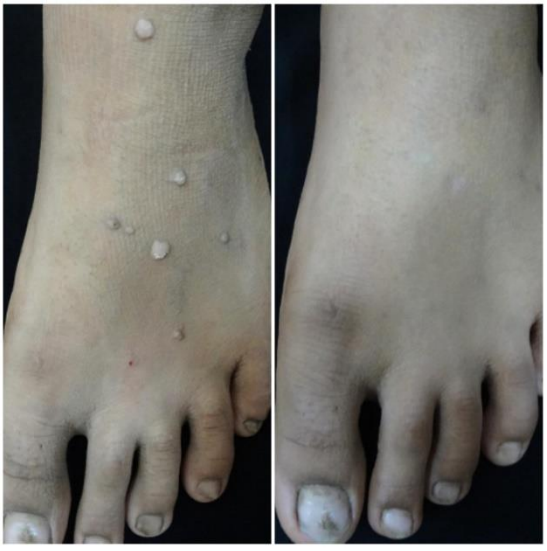

Figure (2): patient treated with acitretin for 3 months

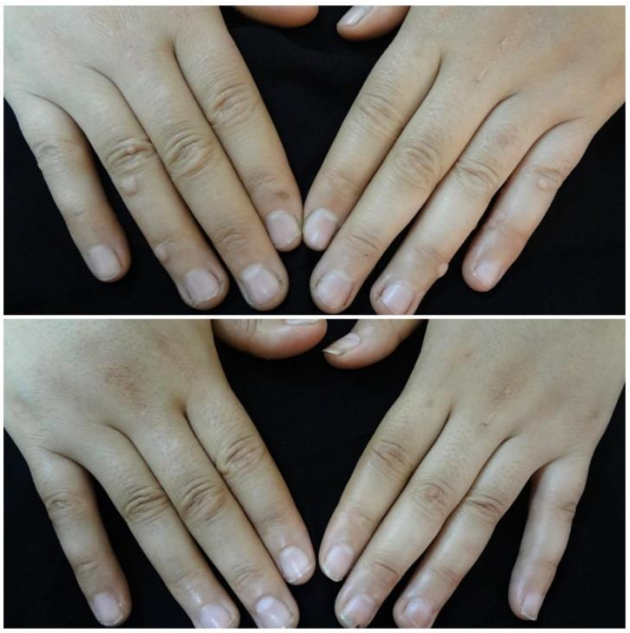

Figure (3): patient treated with isotretenoin for 3 months

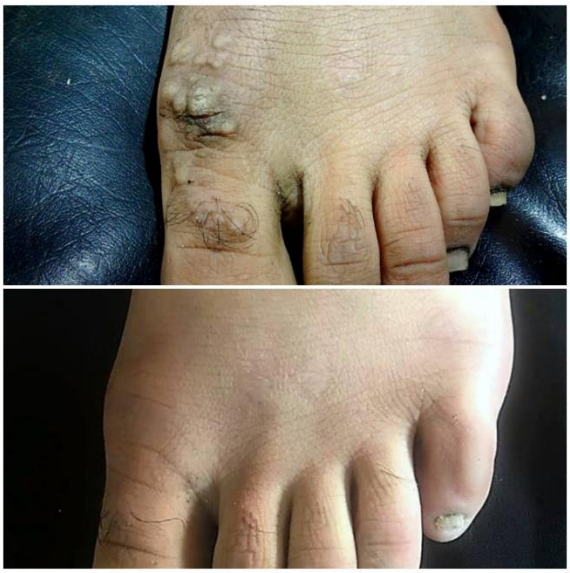

Figure (4): patient treated with isotretenoin for 3 months

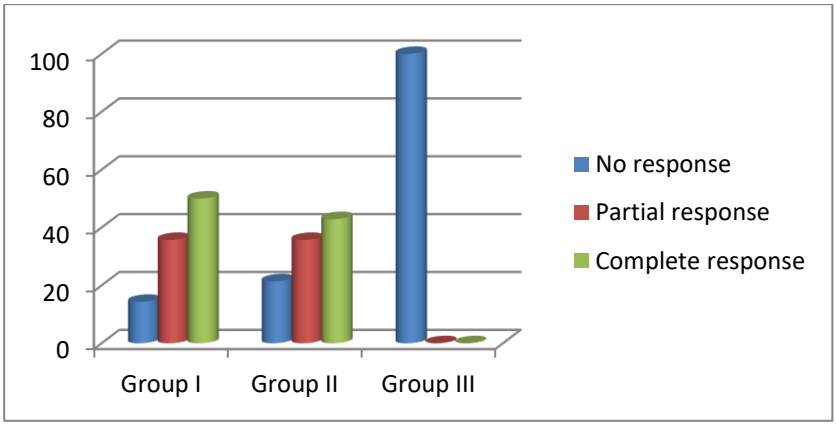

Figure (5): Therapeutic response among the studied groups

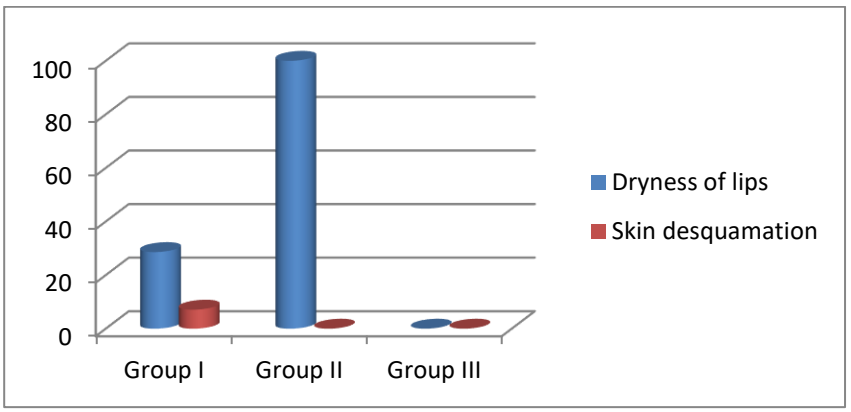

Figure (6): Adverse effects among the studied groups

DISCUSSION

Warts are common, benign, epidermal lesions caused by HPV that infects epithelial tissues of the skin and mucous membranes. Despite the presence of many destructive and immunotherapeutic modalities, treatment of warts still represents a real challenge **[4, 14]**.

Most of the current treatment modalities depend on the ablation of warts. These include, among others, chemical cautery, electrocautery, cryotherapy and laser therapy. This approach might be suitable for patients presenting with single or few lesions. In multiple warts, destructive procedures are inappropriate, impractical and might be associated with high relapse rates and significant side effects like pain, tissue destruction, infection and scarring. This is particularly true in case of children who are highly resistant to the destructive approaches **[3,4]**. Therefore, the use of systemic agents in these cases is highly warranted. Systemic retinoids, including acitretin and isotretinoin have been recently investigated for the treatment of multiple and resistant warts and have been suggested by some authors as favorable, effective, well tolerated and non-invasive alternative modalities for the treatment of multiple and recalcitrant warts**[6,10,12]**.

In the present controlled study, we assessed the efficacy and safety of acitretin versus isotretinoin in treatment of multiple common warts.

In the Acitretin group, 14 patients (50%) achieved complete response. This rate of success was slightly higher than that reported by **Kim et al., [15]** (48%), **Zhang et al., [16]** (42.9%), **Nofal et al., [8]** (40%), and **Nofal et al., [12]** (38.9%). This difference may be attributed to the differences in the number of the studied patients, in the type of warts (all types versus common in our study), and in the nature of the treated warts (recalcitrance in their studies versus non-recalcitrant in our study).

On the other hand, our clearance rate (50%) was much lower than that reported by **El Gharib et al., [17]** who have shown an 80% clearance of common warts in response to acitretin 1 mg/kg/day. This difference may be related to the differences in the study characteristics, including number of the studied patients (20 versus 28 respectively), the use of higher dose of acitretin (1mg/Kg/day) versus a lower dose (0.5 mg /Kg/day) in our study, and site of warts (difficult to treat sites were more common in our study).

Similarly, **Gelmetti et al**. in 1987**[18]** have also reported complete clearance of longstanding multiple and resistant viral warts in 16 out of 20 (80%) immunocompetent children by the closely related compound "etretinate."

In isotretinoin group, 12 patients (42.9%) achieved complete response. The role of isotretinoin, as a single agent, in the treatment of common warts has not been previously evaluated. **Abdelmaksoud[21]** have shown 100% complete response in 14 patients (12 with common warts, 1 with plane warts and one with venereal warts) after addition of a low dose of isotretinoin (0.1-0.2 mg/kg/day) to traditional treatment. This clearance rate was much higher than that reported in our study. Differences in the study population (Indian patients versus Egyptian patients respectively), in the number of the studied patients (14 versus 28 respectively), and the difference between combination therapy and individual therapy may partly explain their higher research success rate compared to our study. On the other hand, **Gupta et al**., **[11]** have reported a much lower response rate where they demonstrated complete clearance of common warts in 3 out of 15 patients (20%) who have received a combination of tretinoin and oral isotretinoin at a dose of 20 mg/day and this low dose may explain the difference between the complete clearance rate in their study and the present work (42.9).

Few studies have evaluated the efficacy of isotretinoin in the treatment of plane warts. **Nofal et al., [6]** have treated 36 patients with multiple plane warts and showed complete response in 16 (44.4%) of them, a closely similar success rate to

that reported in our study. On the contrary, a high clearance rate has been reported by other authors who have used isotretinoin for plane warts; **Olguín-García et al., [22]** (87.5%), **Al-Hamamy et al., [23] (**73%), and **Kaur et al., [5]** (69%). The differences in the treated warts, in the number of the treated patients and in the studied population might explain the higher success rates reported in these studies as compared to ours.

The exact mechanism of action of systemic retinoids (acitretin and isotretinoin) in the treatment of warts is not yet fully explained. However, it has been suggested that they might regulate differentiation and proliferation of keratinocytes **El-Khayat and Hague[10]**.This, in turn, could inhibit the replication of HPV within the affected cells **Nofal et al., [12]**.It has also been observed that an inverse association was found between concentrations of retinoids and HPV deoxyribonucleic acid within infected epithelial cells, proposing an effect on viral replication, leading to remission of warts **Pasmatzi et al., [24]**.Furthermore, it has been suggested that systemic retinoids act as potent immunomodulatory (stimulate IFN-γ and IL-12 production), anti-inflammatory and have apoptotic effects, which help eradicate HPV **Choi et al., [25]**.Moreover, systemic retinoids modify Langerhans cell antigen presentation and surface expression of HLA-DR and CD 11, which have a major role in activation of T- cell that is important for HPV elimination[8].Lastly, some authors have shown that systemic retinoids decrease production of vascular endothelial growth factor by keratinocytes; therefore they might have an important role in the treatment of angiogenesis dependent warts **El Sayed et al., [9]**.No significant relationship between the therapeutic response to isotretinoin and the different clinical variables including, age, sex and duration, size or number of warts was observed in this study. Similar findings have also been reported by **Nofal et al., [6]**.

In the placebo group, complete clearance of warts was not observed in any of the studied patients **(0%)**. This finding of absent or zero response was also reported after the use of oral placebo by **Olguin-García et al., [22]** who have treated 15 patients with recalcitrant flat facial, and **Gupta et al**., **[12]** who have treated 15 patients with common warts.

The results of this study showed that there was a highly significant variation in the therapeutic response between the treatment groups and the placebo group. Although the complete clearance rate of acitretin (50%) was slightly higher than isotretinoin (42.9), the difference was not statistically significant. This might be explained by the hypothesis that acitretin seems to have an effect on keratinocyte differentiation and proliferation that important for inhibition of HPV replication more than isotretinoin[6].However**,** larger, well-controlled studies comparing both agents are highly warranted to give a definite conclusion in this respect.

Concerning adverse effects, dryness of the lips (cheilitis) was the most commonly reported adverse effect in the treatment groups (100% in the isotretinoin group and 28.6% in the acitretin group). Skin desquamation was observed in 2 patients (7.1%) of the acitretin group, while it was not evident in the isotretinoin group. These findings were in agreement with **Olguín-García et al., [22] and Kaur et al., [5] & Nofal et al., [12]** who have reported that the most common observed side effects of oral isotretinoin were cheilitis and xerosis, which improved with moisturizing cream and disappeared on stoppage of treatment.

Recurrence was reported in one patient only of the acitretin group and 2 patients of the isotretinoin group. Recurrence of the lesions after complete response by oral isotretinoin was reported by **(Al-Hamamy et al., [23])** in 4 out of 19 patients (21%) and by **(Kaur et al., [5])** in 4 out of 11 patients (36%), and in 4 patients of isolated acitretin group in the study of **Nofal et al., [12]**.This recurrence represents a disadvantage of wart therapy by systemic retinoids that has no antiviral activity and can be explained by the hypothesis that retinoids act through modulation of keratinocyte differentiation and proliferation; a process that may be reversed after stoppage of therapy**[10]**.However, the small sample size and the short follow-up time make it difficult to give a clear conclusion about the recurrence rate in the present study.

In this respect, it is worthy of note that some authors make a combination therapy of systemic retinoids and intralesional immunotherapy such as Candida antigen to increase the efficacy and decrease the recurrence rate through the sustained long term immunity induced by the intralesional antigen immunotherapy**[6,8]**.

Recommendations: Further studies on a large scale of patients are recommended to determine the efficacy of acitretin and oral isotretinoin in the treatment of different types of multiple warts .Use of higher doses of acitretin and oral isotretinoin (>0.5 mg/kg/day) might be also recommended. Long term follow up of the patients is highly recommended to assess the long term efficacy of each used therapeutic modality in prevention of recurrence.

CONCLUSION

There was a highly significant variation in the treatment response between the treatment groups and the placebo group, while there was no significant variation between the two treatment groups although the complete response rate was slightly higher in the

acitretin group than the isotretinoin group. Acitretin could be a promising, effective, well tolerated and non-invasive alternative therapies for the treatment of multiple and recalcitrant warts.

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