1	Comparative efficacy of 50% Trichloroacetic acid solution with 10%
2	Potassium hydroxide solution in the treatment of plane warts
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4	Short title: Trichloroacetic acid versus Potassium hydroxide in plane warts therapy
5	
6	Abstract
7	Background: Warts are very common disorders. Plane warts are caused by Human Papilloma
8	Virus (HPV) occurring mostly in children and young adults. Among the treatment modalities,
9	topical application of trichloroacetic acid (TCA) is age old. Potassium hydroxide (KOH) has a
10	keratolytic effect on virus-infected cells.
11 12	Aims: To compare the safety and efficacy of topical 10% KOH solution with 50% TCA solution in the treatment of plane warts.
13	Materials and Methods: Sixty-four consecutive patients with plane warts were randomly
14	assigned into two groups of thirty-two patients. Group A received 10% KOH solution and group
15	B received 50% TCA solution once weekly until the complete clearance of warts in a maximum
16	period of 12 weeks.
17	Results: In group under treatment with 10% KOH, 24 patients (75.0%) complete response, 5
18	patients (15.6%) moderate response, 2 patients (6.3%) mild response, and 1 patient (3.1%) had
19	no response. In group under treatment with 50% TCA, 28 patients (87.5%) showed complete
20	response, 2 patients (6.3%) moderate response, 2 patients (6.3%) mild response. Statistically no
21	significant difference was found between the therapeutic response to 10% KOH and 50% TCA $(\mathbf{P}, 0, 41)$
22	(P=0.41).
23 24	Conclusion: 10% KOH was found to be equally effective in the treatment of plane warts compared to 50% TCA with the advantage of fewer side effects.
25	Keywords: Plane warts, Potassium hydroxide, Trichloroacetic acid, therapy
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27	
28	Introduction
29	Warts are caused by infection of keratinocytes by human papillomavirus (HPV). The incidence
30	increases during childhood to reach a peak in adolescence and early adulthood then declines
31	rapidly through the 20s and more gradually thereafter [1]. Its prevalence among children has
32	reported to be between 2-20% in different communities [2]. Verruca plana or plane warts are

caused by HPV types 3, 10, 28, and 41, occurring mostly in children and young adults. Sites of
predilection are face, back of hands, and the shins. They are 2-4 mm flat-topped papules and are
erythematous or brown-colored on pale skin and hypopigmented on darker skin [3]. They have
the tendency to koebnerize, especially in the children [3].

37 Diagnosis and treatment of the disease is very important in terms of beauty issues and preventing 38 the proliferation of warts [4]. Today, many different treatments are used to eliminate warts, which 39 include two major groups of medical treatments and surgical procedures [5]. Medical treatments 40 due to the need for continuous use, and skin sensitivities and side effects are not widely popular among patients [4,5]. In addition, surgical treatments have reduced efficacy due to complications 41 42 such as scars and the possibility of recurrence of warts [4,5]. There are many modalities for the treatment of plane warts that includes topical salicylic acid, glycolic acid, 5-fluorouracil, 43 44 isotretinoin gel, topical zinc sulfate solution, citric acid, trichloroacetic acid (TCA), bacillus Calmette-Guérin immunotherapy, curettage/electrodessication, and cryotherapy [6-10]. Most 45 46 treatments focus primarily on the destruction or removal of visible lesions or on the induction of 47 cytotoxicity against the infected cell. Among these agents, TCA and potassium hydroxide (KOH) are less stimulant and cause less scar [11, 12]. 48

TCA is a topical destructive agent and causes hydrolysis of cellular proteins leading to cell death.
It is effective in treating common, cervical, genital, and anal warts in the concentrations of 7080% and has response rates comparable to cryotherapy [11, 12]. Low concentrations (10-30%)
are used for the treatment of common warts and superficial peeling. The advantage is the
complete lack of systemic toxicity; however, a few local effects such as pain, burning,
hyperpigmentation, and rarely scar formation may occur [13].

55 Potassium hydroxide is a strong metallic base used in the diagnosis of fungal infections, Whiff 56 test for bacterial vaginosis, treatment of male genital warts, and the treatment of molluscum 57 contagiosum in children [14-17]. It acts by its keratolytic effects that lead to the destruction of virus-infected cells causing resolution of warts. Potassium hydroxide is less irritating, less 58 59 painful, less scar forming, and can be safely used in children too. Rarely, side effects such as itching, erythema, and dyspigmentation may be seen. KOH holds better promise for the 60 61 treatment of warts according to a few studies [18]. Hence, it was felt worthwhile exploring this agent for the treatment of plane warts. 62

The aim of this study was to compare the efficacy and safety of topical 10% KOH with 50%
 TCA in the treatment of plane warts.

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Materials and Methods

A randomized, controlled trial was conducted at the Department of Dermatology, Ahvaz Imam 67 68 Hospital, Southwest Iran, during August 2017 to February 2018. A total of 64 patients with age more than 4 years and plane warts ranging from 3 to 30 in number were included in the study. 69 Pregnant and nursing women, patients with hypersensitivity to KOH or TCA, patients currently 70 using any treatment for warts within the last 1 month, patients with comorbid conditions such as 71 72 diabetes mellitus or immunosuppression were excluded from the study. Patients are divided into 2 groups A (10% KOH) and B (50% TCA). Each groups contains thirty-two patients and 73 matched with respect to the age and sex. A four random permutation method was chosen to 74 75 select the patients for both groups. Informed consent form was taken and ethical clearance 76 obtained from the University Ethical Committee (IR.AJUMS.REC.1396.703). The diagnosis of plane warts was made clinically with special attention to the morphology of lesions and loss of 77 78 skin markings over the lesions. Location, size, and number of warts were recorded.

Group A received topical 10% KOH solution and group B received topical 50% TCA solution
once weekly by the physician. In both groups, a cotton-tipped toothpick dipped in the solution
was applied once to the wart under Vaseline cover of surrounding skin, keeping it perpendicular
to the skin surface. The patients were observed for 15 min for any side effects. The therapy was
continued until the completion of 12 weeks or till all the lesions cleared, whichever was earlier.
Both the groups were examined at the end of 4 weeks, 8 weeks, and 12 weeks to evaluate the
response to treatment and for any side effects.

Clinical resolution of the warts was determined by objective responses. Patients, physician and
those who measured the results did not know how to place patients in the groups, as well as the
drugs were prepared similarly in terms of appearance (packaging, color and odor).

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On follow ups, number and size of the warts were measured to use for classification of results.

90 Based on physician's perception of overall percentage of resolution of warts, patients were classified as complete responders: Complete disappearance (100%) of all the warts both in size 91 92 and number, partial responders who were in turn classified as moderate responders: More than 50% (51-99.9%) reduction in number of warts, mild responders: <50% (1-50%) reduction in 93 number of the warts and non responders: No reduction in the number. 94 Data analysis was performed using SPSS version 24. Mean and standard deviation for 95 quantitative variables and absolute and relative frequencies for qualitative variables were 96 determined. The therapeutic efficacy level in the two groups was compared with the chi-square 97 test and the significance level was 0.05. 98

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Results

100 A total of 64 patients (32 in each group) were finally assessed at 12 weeks. Twenty-nine (45.3%) 101 patients were males and 35 (54.7%) were females. Age of the patients ranged from 4 years to 51 102 years, duration of warts from a week to 5 years, number of warts varied from 3 to 30, and size of 103 smallest wart ranged between 1 and 2 mm. The wart location and demographic variables of each 104 group have been collected in Table 1. Both the groups were comparable with respect to different 105 independent variables including sex, age, number, size, and duration of lesions (P > 0.05). No 106 patient had any comorbidities or any state of immunosuppression.

Study results at 12 weeks showed that in KOH group, 24 patients (75.0%) had complete 107 response, 5 patients (15.6%) moderate response, 2 patients (6.3%) mild response, and 1 patient 108 109 (3.1%) had no response. In TCA group B, 28 patients (87.5%) showed complete response, 2 patients (6.3%) moderate response, 2 patients (6.3%) mild response. Statistically no significant 110 difference was found between the therapeutic response to 10% KOH and 50% TCA (P=0.41) 111 [Table 2, Figure 4]. However, it was noticed that the percentage of patients showing complete 112 clearance (100% response) was more in TCA group which was 87.5% as compared to 75% in 113 KOH group but no statistical significance was found. On analysis, the average percentage 114 reduction in number of warts in two groups showed no statistically significant results (P = 115 0.41)[Table1,2]. 116

On comparison of the response in the two groups based on the site of warts, size of warts, sex of patients, age of patients, and duration of disease no statistical difference was observed (*P* > 0.05). Other information such as time to improve, logistic regression and treatment efficacy have

been mentioned in table 3, 4 and figure 3, 4, 5 and 6.

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121 Burning sensation occurred in 25 patients (78.1%) in KOH group immediately after consumption for a transient period of less than one minute and in 32 patients (100%) in TCA group for a 122 transient time of 1-2 minutes. Erythema was seen in all patients (100%) in TCA group during 123 the procedure which disappeared within 10-15 min. Crust was also seen in 10 patients (31.2%) in 124 KOH group and in all patients in TCA group at the place of consumption. Dyspigmentation was 125 seen in 14 patients (43.7%) in KOH group (hypo-hyperpigmention) and in all patients (100%) in 126 TCA group which was completely resolved during follow-up, except for 2 cases of 127 hyperpigmentation, both of which were children and hyperpigmentation was still evident one 128 month after discontinuation of treatment, but had color reduction. On follow-up of the patients 129 130 with complete response after 2 months, two patients had recurrence of warts in TCA group.

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Discussion

A multitude of therapies is available for the treatment of common warts with varying degrees of 132 success ranging from the age-old destructive treatment to cryotherapy and the newly emerging 133 therapies such as pulsed dye laser, intralesional immunotherapy, and autoinoculation therapy 134 [9,11,19]. However, studies on plane warts are scarce. There are insufficient data available to 135 136 show the efficacy and strength of recommendation for topical destructive or caustic agents which are safer, inexpensive, and easy to use in case of plane warts. This study compared the efficacy 137 of such two well-known agents, 10% KOH, and 50% TCA in the treatment of plane warts. It was 138 noticed that the average percentage reduction in wart number at the end of 12th week, show no 139 difference. 140

In one of the most recent studies, by examining the solution of KOH 5% and the tretinoin lotion
0.1% in 72 patients with plane warts for 6 weeks, Yaghoobi et al. (2016) showed that 59.8% in
the KOH group and 64.1% in the tretinoin group decreased lesions. Side effects in the KOH
group were slightly higher than the tretinoin group [20]. In our present study, the efficacy of both

drugs was higher than that of Yaghoobi *et al.*, while there was no significant difference between
the two groups like their study.

Al-Hamdi and Al-Rahmani [18] compared the effects of 5% and 10% KOH on plane warts with 147 once daily application for 4 weeks. Patients under treatment with 5% KOH showed 80.3% 148 149 complete response in comparison with 82.1% of 10% KOH group. Nearly 14.7% showed partial 150 response and 3.15% showed no response in 10% KOH group. The difference in the cure rate for 151 patients showing complete disappearance was not significant at the end of therapy. However, 5% 152 KOH solution showed a slower action in comparison with 10% KOH solution. In addition, the recurrence rates of warts among patients showing complete response were 5.8% in 5% KOH 153 group versus 5.1% in 10% KOH group. all the warts in the study by Al-Hamdi and Al-Rahmani 154 were located on the face. This study has closer efficacy to the current study, and it can express 155 more general findings in the effective use of these drugs. 156

In another single-blinded clinical trial by Pezeshkpoor et al., [12] 62 patients with common warts 157 158 were randomly divided into two groups and were applied 80% TCA or 35% TCA once per 159 week until complete clearance of the lesions for a maximum duration of 6 weeks. Results showed good response rate 46.7% in group 80% and good response rate 12% in group 35%, 160 161 which was significant in improvement between the two treatment groups. Improvement was greater with a higher concentration of TCA solution (80%). The results showed that 35% TCA 162 had a lower clearance rate seen at the end of 6 weeks (12%) which is almost similar to our study 163 164 (11.11%) at the end of 12 weeks. It can be interpreted that more time is probably needed for TCA to show complete response or higher concentration (>35%) can be tried. The present study 165 showed more efficacies compared to the study of Pezeshkpoor and examined the wider variables 166

167 Review of literature shows that TCA in higher concentration (60-80%) has equal cure rates in
168 genital warts compared to cryotherapy [11]. The British Association of Dermatologists
169 guidelines suggest 50-80% TCA weekly application for 8 weeks for treating hand warts [21].

A study by Taner *et al.* (2007) treated 51 women with genital warts with TCA 85%, showed a
good response to TCA with high efficacy and low morbidity [22]. Although the type of warts
was different in their study and, the effective use of the referred drug was mentioned with a
common goal, such as the present study.

In another study by Jayaprasad *et al.* (2016) by examining 60 patients with plane warts treated by
30% TCA or 10% KOH, the therapeutic efficacy of KOH was better at the end of 4 and 8 weeks
but at the end of 12 weeks, there was no difference between two groups [23]. The main
difference between their study and the present study was the difference in the efficacy of the
drugs at the end of 4 and 8 weeks. The follow-up of patients was also more in that study that
could also examine differences of both groups in the long term, whereas this is not the case in
this study.

Also, the use of non-pharmacological methods along with KOH has also shown that this drug is effective and competitive and comparable with other methods for the improvement of patients, including Asadi *et al.* in 2016 in Iran divided 70 patients with warts into two groups of CO2 and KOH laser recipients, which the results showed that88.9% in both groups were fully cured and the efficacy of the two methods was statistically similar [24].

Similarly, in the study of Cengiz *et al.*, patients with plane warts were divided into three groups:
cryotherapy, TCA 10% and TCA 25% that the response to treatment was similar in three groups,
and finally 10% TCA was introduced as a more convenient and safe method [25].

Finally, in the study of Layegh *et al.* 60 women with genital warts received 80% TCA or cryotherapy. the response to treatment in the TCA group was 96.5% and in the cryotherapy group was 93.1%. Relatively, TCA had a faster efficacy in the treatment process [26].

Overall findings indicate that KOH and TCA could be used as safe and effective choices, notonly in comparison with other drugs, but also in comparison with other therapeutic methods.

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Conclusion

This study showed that use of 10% KOH solution and 50% trichloroacetic solution in patients with plane warts could effectively improved plane warts. Both the agents are less expensive, easy to apply, and well suited for the self-treatment of plane warts by the patients. Hyperpigmentation seen with 50% TCA may make it less promising in the treatment of plane warts over the face in

199	young females. Also, 10% KOH can be considered as an effective, safe, cosmetically acceptable,
200	and first line therapy for plane warts in immune competent individuals.
201	Limitations of the study
202 203 204	The sample size was not enough to compare the results of drugs efficacy in generalized population. Small population size led to small sample size, which is due to limited number of medical centers.
205	Recommendation
206 207 208 209 210	We recommend bigger cohorts to have more accurate results. Agents could have been used twice weekly rather than once weekly for better results. Future studies are recommended to evaluate more variables with larger samples size and wider medical centers. More control group can be considered along with the case group or non-therapeutic methods can be used in comparison with the case group.
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212	Ethical and consent: Informed consent form was taken and ethical clearance obtained from the
213	University Ethical Committee (IR.AJUMS.REC.1396.703).
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302	Defore treatment with 500/ TCA								





Before treatment with 10% KOH



Table 1. General characteristics of the patients in group A & B

Variables		Group A	Group B	Total	p-value
Age (years)		19.25±12.27	25.70±15.54	22.42±14.23	0.07
Gender	Male	(46.9%) 15	(46.9%) 15	30 (46.9%)	0.69
	Female	(53.1%) 17	(53.1%) 17	34 (53.1)	
Disease tim	e (months)	16.50±18.19	7.32±8.77	11.91±14.9	0.01
Warts n	umber	10.92 ± 8.44	12.75±10.20	11.87±9.35	0.46
Minimum	size (mm)	1.0±0.00	1.03±0.17	1.01±0.12	0.32
Maximum	size (mm)	2.59±1.62	2.43±1.56	2.51±1.58	0.69
Anterior	Head and	(65.3%) 21	(56.3%) 18	39 (60.9)	
Location Neck					
		(3.1%) 1	0 (0.0%)	1 (1.6)	
Limbs		(12.5%) 4	2 (6.3)	6 (9.4)	0.62
Head and		(3.1%) 1	3 (9.4)	4 (6.3)	
Neck &					
Limbs					
PosteriorHead andLocationNeckTrunk		(3.1%) 1	0	1 (1.6)	
		(3.1%) 1	0	1 (1.6)	0.54
	Limbs	(21.9%) 7	(37.5%) 12	19 (29.7)	

Table 2. Efficacy of treatment in two groups

Time	Efficacy	Group A		Gr	Group B	
		N	%	N	%	
Week 4	Complete	14	43.8%	14	43.8%	
	response					
	No response	1	3.1%	0	0.0%	0.46
	Response less	12	37.5%	9	28.1%	_
	than 50%					
	Response more	5	15.6%	9	28.1%	_
	than 50%.					
Week 8	Complete	23	71.9%	24	75.0%	
	response					
	No response	1	3.1%	0	0.0%	0.79
	Response less	2	6.3%	2	6.3%	_
	than 50%					
	Response more	6	18.8%	6	18.8%	_
	than 50%.					
Week 12	Complete	24	75.0%	28	87.5%	
	response					
	No response	1	3.1%	0	0.0%	0.41
	Response less	2	6.3%	2	6.3%	_
	than 50%					
	Response more	5	15.6%	2	6.3%	_
	than 50%.					
Total	Complete	24	75.0%	28	87.5%	
	response					
	No response	1	3.1%	0	0.0%	0.41
	Response less	2	6.3%	2	6.3%	-
	than 50%					
	Response more	5	15.6%	2	6.3%	-
	than 50%.					

Table3. Time to improve										
p- value	p- value Index (time to improve/week)									
	Std.	Mean	Max	Min	N					
	3.75	6.37	12.00	2.00	32	A				
0.73	3.18	5.81	12.00	2.00	32	B				
	3.46	6.09	12.00	2.00	64	Total				

Table4.Logistic regression to examine the relationship between different factors
 354 and improvement

%95 CL		(OR)	Р	df	Wald	S.E.	B	Variable
Upper	Lower							
10.660	.328	1.870	.481	1	.497	.888	.626	Gender
1.205	.974	1.083	.141	1	2.172	.054	.080	Age
1.016	.923	.968	.190	1	1.719	.025	032	Duration of infection
2.188	.620	1.165	.635	1	.225	.322	.153	Largest dimensions
2.188	.620	1.165	.635	1	.225	.322	.153	Smallest dimensions
1.009	.906	.956	.100	1	2.709	.027	045	Number
13.405	.352	2.171	.404	1	.696	.929	.775	Medication









