

## Effect of aloe vera gel on healing peristomal skin complications in patients with colostomy and ileostomy

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**A** – Study Design, **B** – Data Collection, **C** – Statistical Analysis, **D** – Data Interpretation, **E** – Manuscript Preparation, **F** – Literature Search, **G** – Funds Collection

**Summary Background.** Peristomal skin complications are major problems that have a great effect on the quality of life of patients with colostomy and ileostomy. Therefore, there is a need to use safe products with the least side effects to soothe these complications and reduce pain. Nowadays, the use of aloe vera in the treatment of different diseases and skin problems is on the rise, with a significant positive effect.

**Objectives.** In this study, the effect of topical use of this medicinal plant on peristomal skin complications was investigated.

**Material and methods.** The study sample consists of patients with colostomy and ileostomy who had referred to selected clinics in Shiraz. The control group used standard treatments, but the experimental group used aloe vera gel instead. The convenient sampling method was used. The participants were divided into experimental and control groups via random allocation by the even and odd method. The control group used standard treatments, but the experimental group used aloe vera gel instead. For data analysis, statistic tests such as Wilcoxon, U Mann–Whitney, Kolmogorov–Smirnov, *t*-Test and non-parametric tests were used.

**Results.** There was no significant difference between the experimental and control groups from the point of view of demographic variables and clinical characteristics. The rate of peristomal skin complications before the intervention was not significantly different between the two groups. In the experimental group, the rate of peristomal skin complications after the use of aloe vera gel decreased significantly ( $p = 0.008$ ). In the control group, there was also no significant difference in the rate of peristomal skin complications before and after the intervention ( $p = 0.604$ ).

**Conclusions.** Regarding the healing of peristomal skin complications in both groups in this study and the few side effects of aloe vera gel, being economical and having the ability of home use by patients, the use of aloe vera gel can be useful as an efficient method in the treatment of peristomal skin complications.

**Key words:** aloe vera, surgical stomas, skin care.

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## Background

More than 1 million people in North America live with a permanent ostomy, and about 100,000 new ostomy surgeries are performed each year in response to a variety of conditions, including cancer and certain gastrointestinal diseases [1, 2]. Intestinal stoma is a procedure used to treat different situations like congenital disorders, gastrointestinal polyposis, ischemic disorders, necrotizing enterocolitis, obstructive disorders, radiation-induced enteritis, surgical faults like bowel perforation, acute diverticulitis, rectum cancer, trauma or inflammatory bowel diseases. This treatment approach can be permanent or temporary, which poses many challenges to the quality of life and peoples' activity [3, 4]. The purpose of an ostomy is to relieve pain and discomfort, but in many cases, an ostomy increases patients' concern and causes enormous stresses [4]. Ostomy complications include bleeding, laceration, prolapse, mucocutaneous separation, retraction, stenosis, necrosis and different peristomal skin problems [5]. Skin rashes and skin brittleness are general problems for those who live with colostomy or ileostomy [6]. It is estimated that more than three-quarters of persons living with an ostomy develop peristomal skin problems [7]. Different methods, such as skin protective powder and inflammatory inhibitors like topical steroids, are used to treat peristomal skin problems [8].

Nowadays, the approach is to use herbal medicines as an adjuvant to chemical medicine and as alternatives in some cases, which has attracted the attention of many researchers. Amongst medicinal plants, aloe vera is helpful for skin disorders and is highly regarded in the treatment of many wounds and skin lesions due to its anti-microbial properties [9].

## Objectives

In this study, the effect of this medicinal plant on peristomal skin complications was investigated.

## Material and methods

This is a semi-experimental interventional study. This study includes patients with colostomy and ileostomy who referred to selected clinics in Shiraz from March to November 2017.

According to a pilot study, to reach the objectives, the sample size was determined at 26 patients (13 in each group) using the following formula:

$$n = \frac{(S1^2 + S2^2) (z1 - \alpha2 + z1 - \beta)2}{d^2}$$

$$d = \mu1 - \mu2 = 2.34, \alpha = 0.05, 1 - \beta = 0.8$$

$$z1 - \alpha2 = 1.96, z1 - \beta = 0.84, S1 = 2.07, S2 = 2.24$$

$$\mu2 = 4.09, \mu1 = 1.78$$



However, considering a possible dropout of 20% ( $pnn \times = '11$ ) and to increase study accuracy, the sample size was determined at 15 participants in each group.

Sampling was done *via* the convenient method. The study objectives were then explained, and all the participants took part in this study after signing a written informed consent. An allergy test was performed for all the patients, and none of the participants had an allergy. Patients with an odd number (from the viewpoint of selection sequence number) were placed in the experimental group, and patients with even numbers in the control group. Inclusion criteria were as follows: willingness to participate, having colostomy and ileostomy, having peristomal skin complications, with a 2–15 score based on the DET score scale (Discoloration, Erosion, Tissue overgrowth score scale), being at least 18 years old, not having an autoimmune disease, immunodeficiency, their last radiotherapy session no less than 6 months prior, not having a known allergy to aloe vera gel (in the experimental group, an allergy test was carried out before the first use of aloe vera gel). Exclusion criteria were as follows: unwillingness to continue cooperation, tumor relapse in the area in patients with an ostomy caused by cancer, using another product on the observed area and worsening of peristomal skin condition during the intervention.

The data gathering tools were a demographic information form and DET Score scale form. Demographic information included age, gender, marital status, locality, education, average monthly income, type of disease and underlying diseases. The DET Score scale form was used to analyze the rate of peristomal skin complications. The validity and reliability of DET score tools were confirmed in a study by “Jemec G” and “Martins L” et al. under the title “Assessing peristomal skin changes in ostomy patients: validation of the Ostomy Skin Tool” [10].

The method to determine the rate of skin complication was based on the following scale:

In step 1, the peristomal skin was examined and was evaluated based on the descriptions in each of the three domains (discoloration, erosion and tissue overgrowth).

The maximum points in each domain were determined by 3 points for the size of the affected area and 2 points for the severity.

In step 2, the size of the affected area in each of the three domains was assessed as follows.

If there was no injury, the point was 0. If the injury was less than 25%, the point was 1, between 25% and 50%, the point was 2, and for more than 50%, the point was 3. It should be noted that the area was defined as the peristomal skin area covered by the adhesive.

The severity of injury in each domain was then assessed.

If there was no discoloration, then the skin was considered to be healthy. The area score was 0, and the total DET score was 0.

If there was discoloration, the area affected and the severity within this domain and in the other two domains were assessed.

A similar method was used for other complications such as erosion or tissue overgrowth.

In step 3, the total score was calculated (maximum 15) by adding all the sub scores from each domain.

DET score assessment tools were completed by the researcher. The patients were trained on how to apply aloe vera gel, and they were told to use aloe vera gel with the changing of each bag for 6 weeks. Follow up calls were done every 3 days to ensure that the aloe vera gel was used after each bag change. At the end of 6 weeks, the healing process was investigated by DET score tools. Analysis of the data was carried out via statistics tests such as Wilcoxon, U Mann–Whitney, Kolmogorov–Smirnov, *t*-Test and non-parametric tests.

## Ethics approval and consent to participate

The study is performed according to the Helsinki principals of ethics. All patients signed written consent. The study was approved by the Ethics Committee of the Shiraz University of Medical Sciences under the code IR.SUMS.REC.1395.195.

## Results

Based on the data in Table 1, of the 30 participants in this study, 43.3% were men, and 56.7% were women. 43.3% were under the age of 50. The age range of 41–50 was the most frequent at 33.3%. Based on the data in Table 2, the mean score rate of peristomal skin complications amongst all the participants in this study was  $6.23 \pm 3.18$ . The index in the control group was  $6.53 \pm 3.11$ , and in the experimental group, this was  $5.93 \pm 3.33$ . By using the U Mann–Whitney test, there was no statistically significant difference between the control and experimental groups before the intervention from the viewpoint of skin discoloration rate, tissue overgrowth and peristomal skin complications ( $p > 0.05$ ). However, the skin erosion rate in the control group was more than the experimental group before the intervention ( $p < 0.05$ ). Based on the data in Table 3, the mean score rate of peristomal skin complications in the control group was  $2 \pm 2.64$ , and in the experimental group, this was  $3.40 \pm 4.73$ , 6 weeks after the initiation of the study. This index was  $2.70 \pm 3.83$  for all participants in this study. Based on Wilcoxon test statistics (significant at an error level less than 0.01), the conclusion was that peristomal skin complications after using aloe vera gel were statistically significant with a 0.99% confidence coefficient ( $p = 0.008$ ). This means the rate of peristomal skin discoloration after the intervention had significantly decreased in comparison to the baseline ( $p = 0.001$ ).

**Table 1. Frequency distribution of various demographic traits of the study population in the experimental and control groups**

Group variable		Control group (15 pt)		Experimental group (15 pt)		Total number of patients in the two groups (30 pt)		p
		Frequency	%	Frequency	%	Frequency	%	
Gender	male	8	53.3	5	33.3	13	43.3	0.27
	female	7	46.7	10	66.7	17	56.7	
Age/year	30–50	7	46.7	6	40	13	43.3	0.86
	51–70	6	40	8	53.3	14	46.7	
	> 70	2	13.3	1	6.7	3	10	
Marital status	married	13	86.7	14	93.3	27	90	1
	single	1	6.7	0	0	1	3.3	
	widowed	1	6.7	1	6.7	2	6.7	
Education	less than high school grade	10	66.7	7	46.7	17	56.7	0.62
	high school grade	2	13.3	3	20	5	16.7	
	more than high school grade	3	20	5	33.3	8	26.7	

**Table 1. Frequency distribution of various demographic traits of the study population in the experimental and control groups**

Group variable		Control group (15 pt)		Experimental group (15 pt)		Total number of patients in the two groups (30 pt)		p
		Frequency	%	Frequency	%	Frequency	%	
Average monthly income/Rial	< 15 million	15	100	11	73.3	26	86.7	0.21
	15–25 million	–	–	3	20	3	10	
	> 25 million	–	–	1	6.7	1	3.3	
Type of disease	colon cancer	9	60	13	86.7	22	73.3	0.19
	bowel obstruction	2	13.3	2	13.3	4	13.3	
	bowel trauma	4	26.7	0	0	4	13.3	
Underlying diseases	hypertension	1	6.7	1	6.7	2	6.7	0.5
	diabetes	3	20	0	0	3	10	
	hypertension and diabetes	2	13.3	3	20	5	16.7	
	other	2	13.3	1	6.7	3	10	
	without underlying diseases	7	46.7	10	66.7	17	56.7	

**Table 2. Comparison of the mean rate of peristomal skin complications before intervention between the control and experimental groups**

Variable	Control group (n = 15)		Experimental group (n = 15)		All patients of the two groups (n = 30)		p
	Mean ± SD		Mean ± SD		Mean ± SD		
Skin discoloration (D)	3.27 ± 1.33		4.07 ± 1.16		3.67 ± 1.29		0.138
Skin erosion (E)	2.73 ± 1.53		1.68 ± 1.13		1.93 ± 1.78		0.012
Tissue over growth (E)	0.91 ± 0.53		1.44 ± 0.73		1.19 ± 0.63		0.914
Skin complications (D+E+T)	6.53 ± 3.11		5.93 ± 3.33		6.23 ± 3.18		0.555

**Table 3. Comparison of the rate of peristomal skin complications before intervention and 6 weeks after intervention in the experimental group and control groups**

Variable	Before n = 15		After n = 15		Wilcoxon test	
	Mean ± SD		Mean ± SD		Test statistics Z	p
<b>Experimental group</b>						
Peristomal skin discoloration (D)	4.07 ± 1.16		1.92 ± 1.87		-3.336	<b>0.001</b>
Peristomal skin erosion (E)	1.68 ± 1.13		1.79 ± 0.93		-0.677	0.498
Peristomal the tissue overgrowth (T)	1.44 ± 0.73		1.59 ± 0.6		-0.577	0.564
Peristomal skin complications (D + E + T)	5.93 ± 3.33		4.73 ± 3.4		-2.637	<b>0.008</b>
<b>Control group</b>						
Peristomal skin discoloration (D)	3.27 ± 1.33		1.31 ± 1		-3.508	0.000
Peristomal skin erosion (E)	2.73 ± 1.53		1.10 ± 0.73		-3.314	0.001
Peristomal the tissue overgrowth (T)	0.91 ± 0.53		0.70 ± 0.27		-1.414	0.157
Peristomal skin complications (D+E+T)	6.53 ± 3.11		2.64 ± 2		-3.461	0.001

**Table 4. Comparison of the mean rate of peristomal skin complications after intervention between the control and experimental groups**

Variable	Control group n = 15		Experimental n = 15		All patients of the two groups n = 30		p
	Mean	SD	Mean	SD	Mean	SD	
Skin discoloration (D)	1	1.31	1.87	1.92	1.43	1.67	0.174
Skin erosion (E)	0.73	1.1	0.93	1.79	0.83	1.46	0.857
The tissue overgrowth (T)	0.27	0.7	0.6	1.59	0.43	1.22	0.888
Skin complications (D+E+T)	2	2.64	3.4	4.73	2.7	3.83	0.604

Based on the results of Wilcoxon test statistics (Z) at an error level less than 0.01, the rate of peristomal skin discoloration and the rate of peristomal skin erosion, as well as the sum of the three indexes, the rate of peristomal skin complications in the control group after the intervention showed a significant reduction compared to before the intervention ( $p < 0.01$ ) (Table 3).

Intervention (with the continuation of standard treatment in the control group and using aloe vera gel in the experimental

group) was not statistically significant between the two groups ( $p = 0.604$ ) (Table 4).

## Discussion

A comparison of peristomal skin complications showed that in the experimental group, the total amount of skin complications decreased after the intervention ( $p < 0.05$ ). Among these

complications, skin discoloration showed a significant reduction under the influence of aloe vera gel. However, the erosion and tissue overgrowth indexes did not change significantly.

This study was in line with West & Zhu's study on the efficacy of aloe vera gloves used in the management of occupational dry skin. The results of West & Zhu study showed that dry-coated aloe vera gloves that provide gradual delivery of aloe vera gel to the skin produced a uniformly positive outcome of improved skin integrity, decreased the appearance of fine wrinkling and decreased erythema [11].

In our study, among the three complications, discoloration was the only problem that involved all research participants, and aloe vera gel had a great effect on this complication. Aloe vera gel also decreased the total score of peristomal skin significantly. Discoloration among skin complications had the highest recorded incidence (100% of the patients) and showed the highest amount of healing after the intervention.

Nevertheless, the rate of skin complications was not statistically significant between the two groups after 6 weeks. Although aloe vera gel was useful, it was not superior to standard treatment.

This study was in line with a study by Hajikarimi et al. about the comparison of a novel herbal skin care ointment with regular ointments to treat skin ulcers around the abdominal stoma. The results of their study showed that although the rate of skin ulcers was not statistically significant between the two groups, the herbal ointment similar to regular ointments (Comfeel and Conveen ointments) could help heal skin ulcers around the stoma [12].

Contrary to this finding, the results of a clinical study by Charousaei et al. that compared the healing effects of chamomile solution vs topical steroids on peristomal skin wounds of colostomy patients indicated a significant difference between the two groups, i.e. healing occurred more quickly in the chamomile group than the hydrocortisone group [13].

Our results were also not in line with the results of a study by Mansouri et al. that aimed to assess the effect of an aloe vera solution on stomatitis and its pain intensity in patients undergoing chemotherapeutic procedures. The results of this study showed that there was a significant statistical difference in stomatitis and its pain intensity between the two groups at the end of the study, and the aloe vera solution can reduce stomatitis and its pain intensity [14].

The results of our study were in line with the results of a study by Panahi et al. that aimed to compare the efficacy of an aloe vera/olive oil combination cream and betamethasone 0.1% cream on sulfur mustard-induced chronic skin complications in chemical warfare-injured soldiers. The results of this study showed that both treatments were associated with significant reductions in the frequency of pruritus. The conclusion was that the aloe vera/olive oil cream was at least as effective as betamethasone 0.1% in the treatment of sulfur mustard-induced chronic skin complications [15].

In our study, the insignificant difference between the two groups in the rate of skin complications may be due to the small sample size, short duration of the intervention and the use of efficient treatment in the control group.

## Conclusions

Regarding the healing of peristomal skin complications in both groups in this study and the few side effects of aloe vera gel, being economical and having the ability of home use by patients, the use of aloe vera gel can be useful as an efficient method in the treatment of peristomal skin complications.

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