

Comparison of Standardized Peristomal Skin Care and Crusting Technique in Prevention of Peristomal Skin Problems in Ostomy Patients

Park, Seungmi¹ · Lee, Yun Jin² · Oh, Doo Nam³ · Kim, Jiyun⁴

¹Assistant Professor, Department of Nursing & Research Institute for Basic Science, Hoseo University, Asan

²Wound Ostomy Continence Nurse, Nursing Department, Severance Hospital, Seoul

³Full time Lecturer, Department of Nursing & Research Institute for Basic Science, Hoseo University, Asan

⁴Assistant Professor, Department of Nursing, Kyungwon University, Seongnam, Korea

Purpose: This study was performed to compare the effects of standardized peristomal skin care (SPSC) and crusting technique (CT) on the peristomal skin of ostomates. SPSC was developed by a consensus among the expert group based on a comprehensive review of the relevant literature and hospital protocols. **Methods:** A randomized controlled pilot trial with 2 parallel arms was used. A total of 81 ostomates, who were recruited from a tertiary hospital, completed the baseline, 1-month, 2-month, and 3-month follow-up (SPSC group, n=45; CT group, n=36). SPSC consisted of water cleansing and direct application of ostomy appliances. CT involved crusting hydrocolloid powder and patting with water sponge or protective barrier liquid film. The outcomes of the study were assessed by skin problems, such as discoloration, erosion and tissue overgrowth; the domains of the evaluation tool used in examining the peristomal skin. A generalized estimating equation model was used to examine the effects according to time and group. **Results:** In both SPSC and CT groups, the likelihood of occurrence of discoloration (OR, 1.99; 95% CI, 1.61-2.46), erosion (OR, 1.87; 95% CI, 1.55-2.25) and tissue enlargement (OR, 1.94; 95% CI, 1.36-2.77) increased with time. There was no significant difference in discoloration between the groups, whereas the probability of erosion (OR, 0.38; 95% CI, 0.16-0.89) and tissue overgrowth (OR, 0.09; 95% CI, 0.02-0.55) was lower in the SPSC group than in CT group. **Conclusion:** SPSC was sufficient in preventing peristomal skin problems of ostomates compared to the CT.

Key words: Ostomy, Evidence-based practice, Skin care

INTRODUCTION

A stoma is an artificial opening in the abdominal wall allowing the passage of effluent, such as stool or urine from the body, and is used to remove tumors, repair of bowel injuries and defects, and treat inflammatory bowel disease, e.g., ulcerative colitis and Crohn's disease (Black, 1994). According to the artificial opening site, a stoma can be generally described as a colostomy and an ileostomy.

If a patient has a stoma, he/she should bear the burden of self-care,

such as emptying their own ostomy pouches, and replacing the worn-out skin barrier with a new one. In normal use of ostomy pouching system, the peristomal skin make the base plates of pouching and keeping the peristomal skin clean is a very important issue among ostomates. Unfortunately, a considerable number of ostomates experience one or more peristomal skin problems during their remaining years (Colwell, Goldberg, & Carmel, 2004) and more than one in three visits to ostomy nurses are related to peristomal skin problems (Jemec & Nybaek, 2008). Loss of peristomal skin integrity was related

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Address reprint requests to: Kim, Jiyun

Department of Nursing, Kyungwon University, San 65 Bokjeong-dong, Sujeong-gu, Seongnam 461-701, Korea
Tel: +82-31-750-8822 Fax: +82-31-750-8859 E-mail: jkim@kyungwon.ac.kr

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to chemical injury, mechanical destruction, infectious disease, immunological reactions, and disease-related conditions (Nybaek & Jemec, 2010). The most common peristomal skin problem was irritant dermatitis caused by the chemical injury from wasting products (Nybaek & Jemec; Sung, Kwon, Jo, & Park, 2010). In order to detect skin change early and prevent complications in peristomal site, the most main characteristics of skin problems, such as discoloration, erosion, and tissue overgrowth are described in the standardized ostomy skin tool (Martins et al., 2010).

To reduce severe discomfort in the peristomal site, a crusting technique (CT), making an artificial skin membrane on the peristomal skin was developed (Doughty, 2005). The CT involves the application of hydrocolloid powder and patting with water sponge or protective barrier liquid film to make an artificial skin membrane called crust. This has been internationally applied to ostomates to treat minor peristomal skin problems such as denuded or weeping skin (Clark, 2005; Emory University Wound Ostomy & Continence Nursing Education Program, 2006). On the other hand, CT has been generally used to prevent skin problems even if ostomates have intact peristomal skin, based on only one experimental study in Korea (Park et al., 2003).

However, the materials used in the CT are uninsured items that can impact considerable economic burden to the patients. In addition, patients not well acquainted with making a crust may feel difficulty in applying this method. It has been often reported that CT makes adhesiveness of pouching system weak and the material for CT directly irritates the peristomal skin (Kim, personal communication, November 20, 2009). Skin sealant and skin barrier powder should be used to treat minor skin irritation, and any product can act as an allergen or irritants (Emory University Wound Ostomy & Continence Nursing Education Program, 2006). To date, no further study has examined the protection and prevention effect of the CT among the ostomates in Korea. Owing to the lack of evidence of the CT, Korean Association of Wound Ostomy Continence Nurses (KAWOCN) developed standardized peristomal skin care (SPSC) to enhance the feasible intervention method (Park et al., 2010). SPSC recommends direct pouching on skin to minimize chemical irritation by hydrocolloid powder and application of skin barrier liquid film only for urostomates or fragile skin such as in geriatric patients. This method is very simple and is expected to reduce chemical irritation because this method needs at most skin barrier liquid film. Furthermore,

stronger adhesiveness of SPSC than CT can reduce occurrence of skin problems. There, however, has been no clinical study on this intervention method. This study was performed to compare the effects of the SPSC and the CT on the peristomal skin of ostomates.

1. Study Hypotheses

The hypotheses of this study were that ostomates who underwent the SPSC would have lower incidences of peristomal skin problems, such as discoloration, erosion and tissue overgrowth, compared to the CT group.

METHODS

1. Setting and Sample

This study was conducted at a single tertiary hospital in Seoul, Korea. After obtaining institutional review board approval and consent to participate from each patient in the hospital, two trained Certified Wound Ostomy Continence Nurses (CWOCN) at Y hospital collected data from 81 eligible patients between June 15, 2010 and April 30, 2011.

Those eligible to participate were ostomy patients who (a) were admitted to the hospital in order to undergo colostomy or ileostomy; (b) were 20 to 80 years old; (c) had no diabetes mellitus, vascular disease, or cardiovascular disease; and (d) understood the study objectives and agreed to enroll in the study. Patients who had (a) high possibility of fecal leakage in their ostomy; (b) sensitive skin, such as atopy or allergy; (c) urostomy only; or (d) cognitive problem, were excluded.

Estimating sample size and power based on each expected probability of skin problem that was produced by previous empirical research about SPSC and CT is ideal. However, there was no study performed to measure skin problem after delivering SPSC. Therefore, we determined expected probability of skin problem with reference to the previous studies about ostomy complication in Korea (Park & Kim, 2007; Sung et al., 2010). A sample size of 36 per group was calculated based on an event probability of a 0.4 reduction in the incidence of abnormal peristomal skin status with a type I error of 0.05, 80% power, and 3 time repeated measures. This number was based on the simulation considering the two-group comparison of Bernoulli event probabilities using the logit link (Rochon, 1998) and en-

rollment of a total of 86 patients in this study considering a rate of attrition of about 20%.

Simple random allocation was carried out by allowing each patient to use a fair coin-tossing. When a coin came up heads, the patient was allotted to the SPSC group, and when it did tails, the patient was to the CT group. Contact with patients was initially made in 86 ostomates (45 patients in the SPSC group and 41 patients in the CT group) who started to change their pouching after ostomy surgery. Among them, 81 eligible patients were successfully enrolled. After delivering two skin care methods, the reason for not participating in follow-up data collection included schedule conflict. As a result, SPSC was delivered to 45 patients and the CT to 36 patients.

2. Skin Care Programs and Study Procedures

To develop a standard of peristomal care, clinical guidelines were drafted through a comprehensive review of the relevant literature and hospital protocols. In addition, the proposed guidelines were reviewed by a panel of 6 experts and 20 wound ostomy continence nurses, and were refined based on their suggestions. To deliver SPSC, cleansing the peristomal skin area with tepid water and drying were warranted. Applying the ostomy appliances, such as the flange and pouch, was then followed (Table 1).

On the other hand, CT consisted of sequential methods; cleansing the peristomal skin area with tepid water and drying up, slightly spreading hydrocolloid protective barrier powder on the peristomal skin and beating the spread powder with water sponge or protective barrier liquid film (No Sting™, 3M). WOCNs gave demonstration of each dressing method to the patients in each group and educated

them to change their pouching by themselves. They were also educated to regularly change pouching once per 4 to 5 days and to change it any time if there is stool leakage, detachment of appliances, or any discomfort, such as severe itching or pain, on peristomal area. The follow-up survey after baseline measurement was performed each month for 3 months.

3. Measurements

Abnormal peristomal skin problems included discoloration, erosion, or tissue overgrowth. These three characteristics of the abnormal peristomal skin were measured by Ostomy Skin Tool (OST) (Martins et al., 2010). It is a standardized tool for assessing the peristomal skin and provides a simple assessment scheme for ostomy care nurses to optimize communication between health professionals. It also facilitates consistent monitoring and reassessment of the skin and may help monitor the effect of local or systemic treatments (Martins et al.). Originally, the OST considers both the percentage of the peristomal skin affected under the adhesive barrier and the severity of the problem within each domain. The three domains were assessed to calculate a single composite value, Discoloration, Erosion, Tissue overgrowth (DET) score, which was the score summed of area size and severity. The score of area was assigned between 0 and 3 by the size of affected area (e.g., if a patient has a discoloration less than 25% of the skin covered by the adhesive, then the score of area is 1 and a point of reference is same in erosion and tissue overgrowth) and the score of severity was assigned between 0 and 2. The inter-nurse assessment agreement was $K = 0.84$ (Jemec et al., 2011). In this study, we measured occurrence of three types of skin problems instead of considering affected size and severity on ostomy site, because the rate of occurrence was relatively low and distribution of summing scores from area size and severity were overdispersed.

4. Data Analysis

Chi-square analysis and t-test were used to summarize the sample characteristics and study variables. For the dependent data, chi-square analyses were used to compare the groups in each time (1, 2 and 3 months) and generalized estimating equation (GEE) models tested time effect, respectively. In order to analyze with GEE, the data was rearranged into the time-as-case format. Group and time effects were

Table 1. Procedure of Standardized Peristomal Skin Care and Crusting Technique

Standardized peristomal skin care (SPSC)	Crusting technique (CT)
	1 Cleanse the peristomal skin with tepid water and dry.
1 Cleanse the peristomal skin with tepid water and dry.	2 Dust hydrocolloid powder on the peristomal skin evenly.
2 Apply a protective barrier film in case of urostomy, geriatric patients, and fragile skin.	3 Remove excess powder.
	4 Seal powder by blotting over powder with water-soaked gauze or a moist finger or by spraying with 3M No-Sting to make a crust.

tested using GEE models and variables controlling age, gender, ostomy type and treatment were included in multivariate analysis.

RESULTS

The characteristics of the patients at the baseline were listed in Table 2. The mean age of the patients in the SPSC and the CT group were 55.9 and 56.8 years, respectively. There were no statistical differences in gender, ostomy type, treatment status and diagnoses in both groups.

The skin conditions, such as discoloration, erosion, tissue overgrowth and DET total status, at each follow-up time were presented in Table 3. In both the SPSC and the CT groups, the probability of the occurrence of discoloration and erosion increased with time. On the other hand, the occurrence of tissue overgrowth in the SPSC group had no time dependency. All three skin conditions (discoloration, erosion, and tissue overgrowth) presented with the DET total status in the SPSC group occurred 1.68 times after 1 month. The patients in the CT group had a 2.34 times higher possibility of having a DET status 1 month after the baseline. The chi-square test showed no

significant differences between the groups in terms of the objective skin condition, such as discoloration, whereas proportions of erosion, tissue overgrowth and the DET total status were higher in the CT group at 2 and 3 months.

The GEE to evaluate the differences after controlling several variables was presented in Table 4. There was no significant difference in discoloration between the groups, whereas the possibility of erosion (OR, 0.38; 95% CI, 0.16-0.89) and tissue overgrowth (OR, 0.09; 95% CI, 0.02-0.55) was lower in the SPSC group than in the CT group. The DET status in the SPSC group had a 57% lower possibility than in the CT group. There was evidence of significant increases in discoloration (OR, 1.99; 95% CI, 1.61-2.46), erosion (OR, 1.87; 95% CI, 1.55- 2.25), tissue overgrowth (OR, 1.94; 95% CI, 1.36-2.77), and DET total status (OR, 2.10; 95% CI, 1.70-2.58) in both groups over the follow-up period.

There were no statistical differences in the duration time to pouch change. On the other hand, the patients in the SPSC group paid less than those in the CT group ($t = -2.19, p = .033$) (Table 5).

Table 2. Sample Characteristics at the Baseline (N=81)

	SPSC (n=45)	CT (n=36)	t/ χ^2	p
	Mean (\pm SD) or n (%)	Mean (\pm SD) or n (%)		
Age (yr)	55.9 (\pm 11.6)	56.8 (\pm 12.8)	-.35	.730
Gender			.00	1.000
Male	26 (57.8)	21 (58.3)		
Female	19 (42.2)	15 (41.7)		
Ostomy type			.81	.368
Colostomy	22 (48.9)	14 (38.9)		
Ileostomy	23 (51.1)	22 (61.1)		
Treatment			1.88	.390
Chemotherapy	18 (40.0)	13 (36.1)		
Chemoradiation therapy	19 (42.2)	12 (33.3)		
None	8 (17.8)	11 (30.6)		
Diagnosis*			.196	1.000
Rectal cancer	31 (68.9)	21 (72.4)		
Colon cancer and other type of cancer	10 (22.2)	6 (20.7)		
Crohn's disease and other type of injury	4 (8.9)	2 (6.9)		

*Fisher's exact test.
SPSC=Standardized peristomal skin care; CT=Crusting technique.

Table 3. Discoloration, Erosion, Tissue Overgrowth, and DET Total Status at 1, 2, and 3 Months

	Time to follow-up			Odds ratios for time measure*		
	1 month	2 months	3 months	Odds ratio	95% CI	p
Discoloration, %						
SPSC group	22.2	24.4	22.2	1.67	1.28 to 2.18	<.001
CT group	30.6	44.4	41.7	2.10	1.63 to 2.69	<.001
χ^2 test (between)	.72	3.60	3.54			
Erosion, %						
SPSC group	13.3	20.0	11.1	1.53	1.17 to 1.98	.002
CT group	22.2	47.2	33.3	2.05	1.65 to 2.55	<.001
χ^2 test (between)	1.11	6.80**	5.96*			
Tissue overgrowth, %						
SPSC group	2.2	0.0	2.2	1.53	.42 to 5.59	.521
CT group	8.3	13.9	13.9	1.88	1.33 to 2.64	<.001
χ^2 test (between) [†]	1.59	6.66**	3.97*			
DET total status, %						
SPSC group	22.2	26.7	22.2	1.68	1.29 to 2.18	<.001
CT group	30.6	58.3	47.2	2.34	1.81 to 3.03	<.001
χ^2 test (between)	.72	8.31**	5.63*			

*Reference was initial skin status at the time of randomization (0 month);
[†]Fisher's exact test; * $p < .05$; ** $p < .01$.
SPSC=Standardized peristomal skin care; CT=Crusting technique, DET total status: at least one abnormal skin problem such as discoloration, erosion, and tissue overgrowth.

Table 4. Comparisons between Standardized Peristomal Skin Care and Traditional Crusting Technique for the Protection of Peristomal Skin

	Odds ratio	95% CI	<i>p</i>
Discoloration, %			
Intercept	0.78	0.12 to 4.99	.790
Group*	0.56	0.26 to 1.23	.147
Time*	1.99	1.61 to 2.46	<.001
Erosion, %			
Intercept	0.24	0.02 to 2.71	.249
Group*	0.38	0.16 to 0.89	.026
Time*	1.87	1.55 to 2.25	<.001
Tissue overgrowth, %			
Intercept	0.22	0.00 to 12.61	.462
Group*	0.09	0.02 to 0.55	.009
Time*	1.94	1.36 to 2.77	<.001
DET total status, %			
Intercept	0.51	0.08 to 3.16	.469
Group*	0.43	0.20 to 0.94	.033
Time*	2.10	1.70 to 2.58	<.001

*CT group or baseline is the reference. Controlled variables are age, gender, ostomy type, and treatment. DET total status: at least one abnormal skin problem such as discoloration, erosion, and tissue overgrowth.

DISCUSSION

In this study, a randomized controlled trial was performed to compare the effect of the SPSC and the CT on prevention of peristomal skin problems. During the follow-up period, DET score increased as time went on in both the SPSC and the CT groups. These results in this study were similar to those reported on skin complications in the peristomal area (Kim et al., 1999; Nybaek & Jemec, 2010; Sung et al., 2010).

Discoloration, erosion, and tissue overgrowth occurred more frequently in the CT group. Discoloration, which is just a change of skin color without significant discomfort in patients, showed statistical significance only in univariate model. However, erosion and tissue overgrowth are kinds of skin complications in the ostomy patients. Erosion may easily occur on the peristomal skin by effluent's leakage in the space between the crust and waterproof ostomy skin barrier which is found in the CT.

Tissue overgrowth, which is reported as type of hyperplasia, was not common in the SPSC group, whereas this was observed in the CT group. Hyperplasia frequently occurs in urostomy and rarely does in ileostomy or colostomy (Hampton & Bryant, 1992). Despite the lack of evidence, the occurrence of tissue overgrowth in the CT group can be explained by an action of the chemical constituent of the hydrocol-

Table 5. Characteristics of Ostomy Care

	SPSC		CT		<i>t</i> / χ^2	<i>p</i>
	Mean (\pm SD) or n (%)	Mean (\pm SD) or n (%)	Mean (\pm SD) or n (%)	Mean (\pm SD) or n (%)		
Duration time between ostomy pouch change*, (days)	4.23 (\pm 1.54)	4.12 (\pm 1.33)			.32	.747
Monthly cost for ostomy care [†] , KRW	25,097.5 (17,393.0)	34,512.8 (15,975.1)			-2.19	.033

SPSC=Standardized peristomal skin care; CT=Crusting technique; *Only patients who answer this question were analyzed (n=74, SPSC group=45, CT group=29); [†]Only patients who answer this question were analyzed (n=63, SPSC group=37, CT group=26); KRW=Korean Won.

loid powder, pectin. Hydrocolloid dressing used for the pressure ulcer of stage II and over interacts with wound exudates, absorbs the excess drainage, and accelerates the healing process; This provides ideal environment for formation of granulation tissue (Park, Chun, & Park, 2005). Protective powder spread in the CT is similar to the component of hydrocolloid dressing, which may hasten the formation of granulation tissue on the peristomal skin. Tissue overgrowth makes the patients anxious and creates difficulty in managing ostomy care because of the bleeding tendency in overgrown tissue.

These results suggest that SPSC in lieu of the CT can be applied to the peristomal skin without complications. Discoloration occurred during the follow-up period, which was not significantly different in both groups. On the contrary, the erosion and the tissue overgrowth in the SPSC group were significantly lower than in the comparison group, which indicated a better prognosis in skin complications. From the study by Issberner and Schuren (2004), in addition to the protective film applied by the type of spray or wipe, skin protection products containing petrolatum are quite efficacious in protecting the skin and have high hydration properties. Despite the usefulness and effectiveness of providing a protective barrier to the peristomal skin, stool leakage can cause skin breakdown (Hoggarth, Waring, Alexander, Greenwood, & Callaghan, 2005). Therefore, regular pouching and timely changing appliances are recommended if there is any suspicion of the leakage of feces, effluent or urine (Black, 2007; Nix & Ermer-Seltun, 2004). The most important thing in changing appliances is thorough washing out the skin with soap and water to remove all traces of oil or adhesive. From the main findings and reviews of recommended interventions, cleansing and preventing leakage of stool rather than applying a skin barrier is the key point in intervention to protect the peristomal skin. Future research with a larger

sample size and longer follow-up period, which may reveal the effect of waste leakage and replacement of skin barrier on peristomal skin, is warranted to extend and further validate these promising results. From these results, the SPSC, an intervention using water and timely pouching, is more recommendable than the CT in preventing peristomal skin problems. This is also based on the previous recommendation that skin sealant and skin barrier powder should be used to treat minor skin irritations (Emory University Wound Ostomy & Continence Nursing Education Program, 2006). If ostomates have minor peristomal skin problem, they can apply the CT to treat skin problems. For severe skin problems or other complications, appropriate treatment such as application of silver nitrates or packing dressing according to their etiology can be applied to the ostomates (Emory University Wound Ostomy & Continence Nursing Education Program; Park, Chun, & Park, 2005).

An appropriate treatment for peristomal skin care must be cost effective. Although there was no difference in the duration time to pouch change between the groups, the monthly cost for ostomy care was lower in the SPSC group; it was expected result because the SPSC doesn't need any uninsured items.

The limitations of this study were methods of data collection and intervention delivery. Although inter-rator agreement of OST was high in previous study (Martins et al., 2010), two WOCNs need to check skin condition and decide whether there is skin problem in each patient. However, all of patients didn't contact two WOCNs at the same time because of schedule conflict in this study. In the future research, it is necessary to collect data from each patient and to draw valid diagnoses by many WOCNs. The patients were educated to change their pouching by themselves. Although WOCNs checked dressing procedures and skin condition on follow-up date, there can be individual differences in performing interventions at home among the patients. This could show a little lack of objectivity in assessing skin condition. Despite these limitations, this study revealed that the SPSC was more feasible method for ostomates without skin problem than the CT for prevention of the peristomal skin problem.

CONCLUSION

The SPSC in the form of water cleansing and no adding any protective liquid barrier film or hydrocolloid powder was better in preventing peristomal skin problems of ostomates than the CT. The

study results also showed economic merit of the SPSC. Therefore, WOCNs had better recommend the SPSC to the patient without skin problems. The CT is to be applied only for treating minor peristomal skin problems. Future study needs to be performed to collect more evidences of peristomal skin dressing including the SPSC and to provide adequate intervention protocol for ostomates according to the status of peristomal skin.

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