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CE OSTOMY CARE

Factors Impacting the Quality of Life of People With an Ostomy in North America

Results From the Dialogue Study

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PURPOSE: The purpose of this study was to evaluate skin condition and quality of life following the use of a double-layer adhesive pouching system. This article reports results from North American participants.

DESIGN: The study was an open-label, noncomparative, multicenter study.

SUBJECTS AND SETTING: Seven hundred forty-three persons with ostomies who reside in North America participated in the study.

INSTRUMENTS: A Stoma-Quality of Life (QOL) questionnaire consisting of 20 questions was used to measure health-related quality of life. The Ostomy Skin Tool was used to assess peristomal skin condition.

METHODS: Peristomal skin and health-related quality of life were assessed by WOC nurses at baseline and again after 6 to 8 weeks following the use of a double-layer adhesive ostomy pouching system. The participants recorded self-reported leakage level, presence of peristomal skin disorder, use of appliance type (eg, convex, 1- or 2-piece), and frequency of consultation with the WOC nurse.

RESULTS: Participants experienced a significant decrease in frequency of pouch leakage ($P < .0001$) and accessory use, improvement of skin condition, and overall significant improvement in mean quality of life score (56.8 vs 58.9, $P < .0001$). The greatest change on the Stoma-QOL scores was observed in the quartile of participants with the lowest QOL at baseline. Their QOL scores rose from a mean 43.8 at visit 1 to 50.1 at visit 2 ($P < .0001$).

CONCLUSION: The combination of a regular contact with a WOC nurse and the use of a double-layer adhesive appliance led to a significant reduction in leakage and accessory use, improved skin condition, and significant improvement in health-related quality of life.

Introduction

Creation of an ostomy affects quality of life (QOL) in multiple ways. The QOL among persons living with an ostomy has been addressed in a number of studies,[1-6] and in 2005 an ostomy-specific quality of life questionnaire (Stoma-QOL) was developed and validated.[7] Although the intervention of a WOC nurse has been associated with improved health-related QOL, research on the impact of the pouching system remains limited. The Dialogue Study was designed to recruit a global sample in order to identify factors that influence QOL. Data collection focused primarily on skin condition and health-related QOL among persons using the same skin barrier a double-layer adhesive ostomy pouching system SenSura (Coloplast A/S, Humlebaek, Denmark). More than 3000 people with an ostomy and more than 500 WOC nurses from 18 countries around the world participated in the study. North America comprised one-fourth of the participants (n = 743).

The aim of this study was to document peristomal skin condition and health-related QOL when wearing a double-layer adhesive pouching. An additional aim was to evaluate the combined effect of WOC nurse intervention with the pouching system. Furthermore, frequency of consultations, type of appliance and accessories used, self-reported leakage level, and presence of peristomal skin disorders were recorded to assess its influence on health-related QOL.

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Methods

The Dialogue Study employed an open-label, multicenter descriptive design. Participants were solicited via mailers, advertising, and patients seeking care from data collectors. Inclusion criteria were having a colostomy, ileostomy, or urostomy for at least 6 months, and aged 18 years or older. Persons receiving chemotherapy, pregnant, and/or breastfeeding, those with more than 1 ostomy, or individuals using a plug to manage their ostomy were excluded. The study was approved by each participating facility's institutional review board; informed consent was obtained for all participants.

Data were collected during 2 visits: the first visit was used to obtain demographic and clinical information including sex, age, date of ostomy surgery, ostomy type, reason for ostomy, planned or not planned ostomy, temporary or permanent ostomy, current type of ostomy pouching system, frequency and time since last consultation with a WOC nurse, and management with irrigation or not. During visits 1 and 2, data collection included subjects' own assessment of whether a peristomal skin condition was present or not, the number and type of accessories used for pouching such as paste or similar sealing product, lotions, a protective film or sheet dressing, skin cleanser, belt, pouch cover, night bag, tape, or clamp. The frequency of pouch leakage and an evaluation of the current pouching system were obtained on each visit; participants rated their baseline pouching system on visit 1 and their study pouching system on visit 2. In addition, participants were instructed to complete the Stoma-QOL questionnaire. During visit 1, stomal and peristomal skin assessment was conducted by the WOC nurse using the OST. Based upon this assessment, the WOC nurse provided a double-layer adhesive product and instructed the participant how to apply and use the product. The second visit was scheduled 6 to 8 weeks ± 4 days after visit 1; the same WOC nurse collected data at each visit to ensure consistency in peristomal skin evaluation. Participants completed the Stoma-QOL questionnaire and a self-assessment of the pouching system and frequency of pouch leakage on visit 2. Any adverse events that occurred between the 2 visits were recorded during the second visit.

Instruments

The Stoma-QOL questionnaire was used to measure health-related QOL. It was developed and validated specifically for persons with an ostomy.[7] It consists of 20 questions covering 4 domains: sleep, general activity (including ostomy appliance factors), relations to family and close friends, and social relations to people other than family and close friends. The instrument is scored from 0 (worst possible QOL) to 100 (best possible QOL). To minimize bias, participants were asked to complete the questionnaire after instruction from the WOC nurse. Participants placed the completed questionnaire in a sealed envelope before returning to the WOC nurse.

The OST was developed by an international group of 12 expert WOC nurses with advice from a dermatologist. The purpose was to give health care professionals a standardized tool for efficient and effective communication and assessment of peristomal skin condition. The reliability and validity of the OST were assessed by a group of 20 WOC nurses and 5 experts with knowledge in instrument design.[8-10] The OST evaluates the presence and severity of the peristomal skin; it assesses 3 conditions: discoloration (D), erosion or ulceration (E), and tissue overgrowth (T). A DET score is generated with the combined score from each of the 3 domains. Domain scores vary from 0 (normal skin) to 15 indicating severe discoloration, ulcerations or denuded skin, and extensive tissue overgrowth. Participants' peristomal skin conditions were assessed by the same WOC nurse at both visits.

Data Analysis

Descriptive statistics were used to summarize demographic and pertinent clinical data. Change in QOL was analyzed using analysis of covariance, with country and center as random effects, and covariates included categorical variables sex, the frequency of consultations with a health care professional and the type, permanency, and reason for the ostomy. Furthermore, quantitative variables were included as follows: DET score (0-15) at baseline, stoma-QOL at baseline, age at baseline, years since surgery, and degree of leakage relative to the current appliance. Inferential analyses were completed using a 2-tailed analyses; P levels < 0.5 were considered statistically significant.

Changes in DET scores were also analyzed using analysis of covariance, with country and center as random effects. Covariates included sex, frequency of consultations with a clinic, type of ostomy, permanency of ostomy, reason for ostomy, and current type of appliance (1- or 2-piece). Quantitative covariates included DET score (0-15) at baseline, age at baseline, time since surgery, and degree of leakage relative to the current appliance. Change in leakage level score (1-5) was analyzed using the Wilcoxon 1-sample test.

Results

Seven-hundred forty-three persons with ostomies who resided in North America enrolled in the study and completed visit 1. Seventy participants dropped out before visit 2 due to various reasons (7 experienced adverse events, 16 noncompliance, 7 experienced skin problems, 16 experienced pouching system dysfunction, 14 listed other reasons for dropping, and 3 dropped for unknown reasons). Subject characteristics at visit 1 are summarized in Table 1. The mean age of the enrolled participants was 61.4 ± 15.7 years (mean ± SD); 59.1% were women. More than half of the participants (52.5%) had a colostomy and 47.1% had an ileostomy.

TABLE 1.

Baseline Demographics and Characteristics

	N (%)	Mean, y	SD, y	Range, y
Country				
United States	700 (94)			
Canada	43 (6)			
Age	741 (100)	61.4	15.7	18-95
Sex				
Unknown	1 (0.1)			
Male	303 (40.8)			
Female	439 (59.1)			
Time since surgery, all	743 (100)	10.2	11.2	0-64
Type of ostomy				
Unknown	1 (0.1)			
Colostomy	390 (52.5)			
Ileostomy	350 (47.1)			
Urostomy	2 (0.2)			
Reason for ostomy				
Unknown	10 (1.3)			
Crohn disease	119 (16.0)			
Ulcerative colitis	154 (20.7)			
Diverticulitis	67 (9.0)			
Cancer	263 (35.4)			
Other	130 (17.5)			
Planned ostomy				
Unknown	1 (0.1)			
No	196 (26.4)			
Yes	546 (73.5)			
Permanent ostomy				
Unknown	1 (0.1)			
Permanent	685 (92.2)			
Temporary	57 (7.7)			
Baseline QOL, all	722 (100)	56.7	9.7	11.5-82.8
Baseline DET score, all	737 (100)	2.5	2.6	0-15

Abbreviations: DET, discoloration, erosion or ulceration, and tissue overgrowth; QOL, quality of life.

During visit 1, participants were asked how often and when they had their last consultation with a WOC nurse. Thirteen percent of participants reported regular consultation with a WOC nurse. Thirty-two percent never saw a WOC nurse and more than half (55%) of the participants only had a consultation when they felt that it was needed (Figure 1). Fifty-seven percent of the enrolled participants had their last consultation more than 12 months ago.

Participants were asked about their peristomal skin condition during both visits. At the first visit, 29% (n = 216 out of 733; data concerning peristomal skin condition were not obtained from 10 subjects at visit 1) reported experience of a peristomal skin disorder. Assessment by a WOC nurse revealed that 61% of participants had objective signs of a peristomal skin disorder on visual inspection. Two hundred thirty-one (32%) were not aware of having a peristomal skin disorder. A similar pattern was observed on visit 2 when 30% (n = 196 out of 654 patients who completed both visits) did not report a peristomal skin disorder observed by WOC nurse data collectors.

Participants also reported the use of accessories was reduced at both visits. The most widely used accessories were "paste or similar" and "protective film." On visit 1, 87% of participants used accessories versus 66% (n = 451 out of 679) at visit 2; this difference was statistically significant ($P < .0001$). The percentage of participants using 3 or more accessories was significantly reduced from 37% at visit 1 to 14% at visit 2 ($P < .0001$).

Participants self-reported leakage frequency and severity at both visits. When queried on visit 1, 28% (n = 203) stated that they "always" or "often" experienced leakage, 40% (n = 297) reported leaking "sometimes," and 32% (n = 239) stated that they "rarely" or "never" experienced leakage with their current pouching system. At visit 2, the percentage of participants who "always" or "often" experienced leakage was significantly reduced to 16% (n = 105; $P < .0001$). In addition, the number of participants who "never" or "rarely" experienced leakage was significantly lower (59%; $P < .0001$) (Figure 2).

Health-related QOL was assessed at both visits for a number of covariables, for example, skin condition, type of ostomy, reason for ostomy creation, planned or not planned ostomy, and frequency of leakage. The overall mean QOL score increased significantly from 56.8 to 58.9 ($P < .0001$) (Figure 3A). The highest improvement for QOL was obtained for the group of participants with the lowest quartile scores at baseline. In this group, the mean QOL improved significantly from 43.8 to 50.1 ($P < .0001$; Table 2). From all the covariables tested, leakage had the highest average impact on the gain in QOL from visit 1 to visit 2 (Figure 3B). For those who "always" or "often" experienced leakage, the mean gain in QOL was 5.3 and 4.2, respectively.

Peristomal Skin Condition

Peristomal skin condition was assessed by the same WOC nurse at both visits, and the OST was used to calculate a single composite DET score. All categories of peristomal skin disorders improved significantly ($P < .05$) from visit 1 to visit 2 (Figure 3C). The highest improvement was seen in participants suffering from infection-related peristomal skin disorder where the mean DET score improved from 3.8 at visit 1 to a mean DET score of 1.1 at visit 2. Subjects with allergic contact dermatitis had a mean DET score of 4.5 at visit 1 versus mean score of 2.4 at visit 2.

Discussion

Approximately 1 million people living in the United States and Canada have an ostomy and approximately 100,000 ostomies are performed each year in the United States.[11] Clinical experience demonstrates that the stoma and

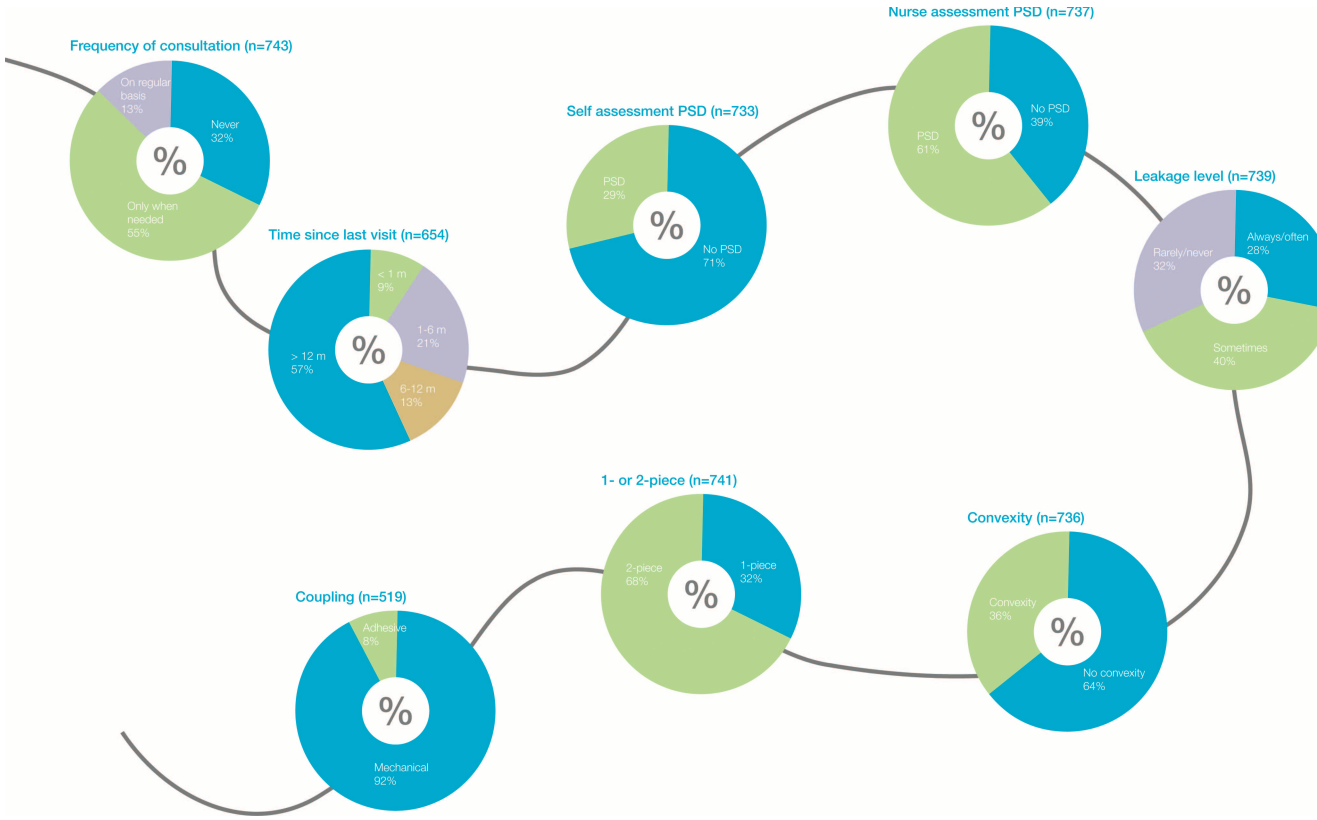

FIGURE 1. "Pearls" of baseline values. A wealth of baseline values was recorded such as "Frequency of consultation," "Time since last visit," "Self-assessment of peristomal skin disorder (PSD)," "Nurse assessment of peristomal skin disorder," "Leakage level," "Convexity," "Use of either 1- or 2-piece pouching system," and "Type of coupling."

abdomen change rapidly during the first 2 months following surgery. Hence, regular follow-up visits with a WOC nurse can be beneficial to modify stoma management and address concerns of living with an ostomy.[1,2] However, only 13% of 743 participants reported regular visits with a WOC nurse and 32% stated that they had never visited a WOC nurse. Reasons for lack of regular follow-up with a WOC nurse may include lack of health insurance,[12] embarrassment, or absence of a "near-by" clinic with certified WOC nurses.[13] In contrast to these findings, results from the global Dialogue Study revealed that 33% of respondents reported regular visits with a WOC nurse.[14]

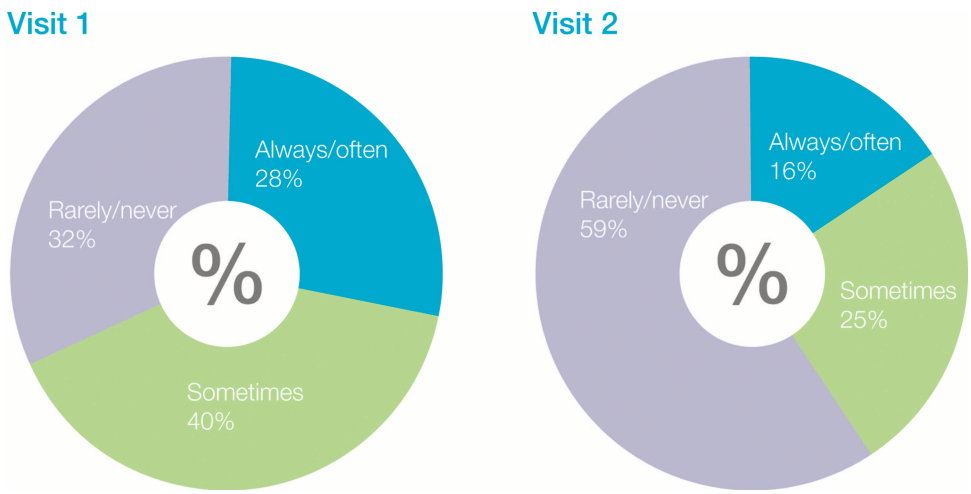

FIGURE 2. Leakage level visits 1 and 2. The leakage level at visit 1 is compared with the leakage level at visit 2, based on the responses from the participants. A remarkably higher percentage experienced "rarely/never" leakage at visit 2 compared with the percentage at visit 1.

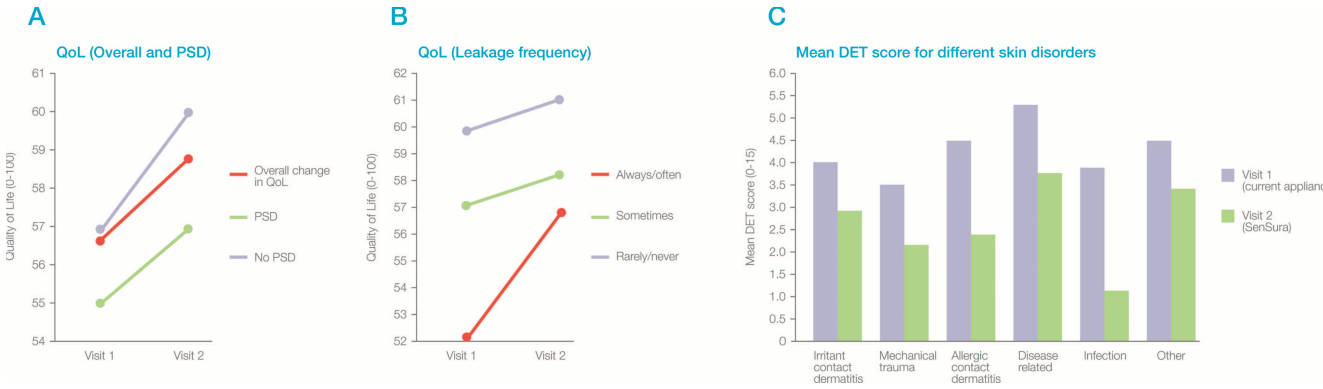

FIGURE 3. Quality of life (QOL) and change in DET (discoloration, erosion or ulceration, and tissue overgrowth) score at visits 1 and 2. (A) The overall change in QOL from visits 1 to 2 is marked by the red line. The green line shows the change in QOL for those who have a peristomal skin disorder (PSD), and the blue line shows the change for those without a peristomal skin disorder. (B) The change in QOL for those who "always/often" experience leakage (red line), "sometimes" (green line), and "rarely/never" (blue line). The highest gain in QOL from visits 1 to 2 is seen for those who "always/often" experience leakage. (C) The mean DET score for different skin disorders is shown for visits 1 and 2. For all types of skin disorders, the mean DET score was improved from visits 1 to 2.

Without professional assistance, people with ostomies may have difficulty correctly fitting their pouching system. Accessories such as paste, rings, and adhesives may be used to ease fitting problems. We found that 87% of participants used accessories at visit 1, and 66% used accessory products on visit 2. This finding suggests that changing the pouching system can reduce the need for accessory products, potentially reducing both cost and time associated with ostomy management.

The frequency and severity of perceived leakage were significantly reduced following the use of the novel pouching system ($P < .0001$). Possible reasons for the observed decrease in leakage and unplanned changes include correct sizing of the appliance, effective management of skin conditions, and instruction received from WOC nurse during visit 1. Leakage of ostomy effluent beneath the adhesive of an ostomy appliance is one of the main causes of peristomal skin disorders.[13]

Despite the prevalence of peristomal skin disorders and their impact on QOL, many participants did not recognize that they have a peristomal skin disorder. We found that 61% of the participants found to have peristomal skin problems on WOC nurse assessment, but only half recognized their skin problem. This finding is consistent with results from the Ostomy Skin Study[13] that enrolled 202 persons with permanent ostomies. They reported that 38% participants diagnosed with a peristomal skin disorder acknowledged a problem with their peristomal skin.

Health-related QOL improved significantly between visits 1 and 2 (56.8 vs 58.9, $P < .0001$). In addition, of all the covariables tested, leakage had the highest impact change in QOL scores. Our results are consistent with those of Pittman and colleagues,[15] who investigated 239 veterans with ostomies and found that leakage impaired health-related QOL. Marquis and colleagues[2] also reported confidence when changing the pouching system was associated with higher health-related QOL.

TABLE 2.

Change in QOL Stratified in 3 Groups

	QOL Values, Mean (SD)		
	Lowest, 25%	Mid, 25%-50%	Highest, 50%
Visit 1 (baseline)	43.8	54.1	64.3
Visit 2	50.1	56.6	64.4
ΔQOL	6.3	2.5	0.1

Abbreviation: QOL, quality of life.

Limitations

Due to study design, we were not able to differentiate the effect of the double-layer pouching system versus the intervention by the WOC nurse. The study period was 6 to 8 weeks; however, it is unknown whether a longer follow-up period is needed to adequately assess the impact of study intervention on certain aspects of health-related QOL. The presented data comprise a combined sample from Canada and the United States. Because Canadian participants comprised only 6% of the study sample, we were unable to analyze results for each country.

Conclusions

This article reports results from North American participants in the Dialogue Study. The combination of a regular contact with a WOC nurse and the use of a double-layer adhesive appliance significantly reduced pouch leakage, accessory use, improved peristomal skin condition, and health-related QOL.

KEY POINTS

✔ The combination of a regular contact with a WOC nurse and the use of a double-layer adhesive pouching system resulted in a significant reduction in leakage and accessory use.

✔ Regular contact with a WOC nurse and the use of a double-layer adhesive pouching system significantly improved peristomal skin condition based on WOC nurse assessment.

✔ Regular contact with a WOC nurse and the use of a double-layer adhesive pouching system significantly health-related quality of life.

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