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Self-care and Health related Quality of Life in patients with drainage enterostomy: a multicenter, cross sectional study.

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Abstract: The current article examined stoma self-care and health-related quality of life in patients with drainage enterostomy, describe clinical and sociodemographic variables and analyze the relations between all of them. Trained interviewers collected data using a standardized form that queried sociodemographic and clinical variables, collected from the electronic medical record, in addition to the Specific Self-Care for Ostomized Patients Questionnaire (CAESPO) and Stoma Quality of life (S-QoL) from January 2016 to January 2017. This was a multicenter, cross sectional study conducted in four hospitals of the province of Castellon (Spain) where 120 participants were studied. Significant differences were found in Self Care according to sex ($p = .043$); married participants show higher score ($p < .01$); also, significant differences according to work activity were observed ($p < .01$). Regarding the clinical variables, differences were observed according to the autonomy of care, the presence of complications in the stoma, the use of irrigation and the type of effluent ($p < .01$). We can highlight the importance of the skills related to self-care by ostomized patients has for a good level of quality of life related to health. In this learning process, the figure of the stoma therapist plays a very important role.

Keywords: Self-care, Self-care monitoring, Quality of life, Stoma care, Health promotion, Nurse – Patient interaction

1. Introduction

Construction of a stoma is an integral part of many abdominal operations performed by general surgeons and others. Its use is common in the treatment of colorectal tumors, trauma, diverticulitis, inflammatory bowel disease, and many other ailments. Colon cancer has become the main cause why patients end up carrying an elimination enterostomy (1). Ostomies generate physical and psychological alterations that require significant adaptation by patients. Ostomized patients will have to modify their lifestyles and learn new skills related to the care of their stoma. This challenge can have a major impact on your health related quality of life (HRQOL).

Thus, patients with a stoma must face serious surgery, the loss of important bodily function, a distortion of their image, and a remarkable and important change in their physical functioning and personal care (2–4). Hence, it is considered that all these changes affect various aspects of patients' lives such as the psychosocial area, sexual

health, body image or cultural and religious beliefs, among others (3,5–10). In fact, these physical and psychological stressors play a very important role in the adjustment to the disease and in the prognosis of it, as well as in the quality of life perceived by the patient (2,11).

More than 65% of new Colorectal Cancer (CRC) cases occurred in countries with high or very high levels of human development; almost half of the estimated new cases occurred in Europe and the Americas (12). In the United States in 2017, there were projections of 135,430 individuals being newly diagnosed with CRC and 50,260 patients dying from the disease (13). Incidence rates of CRC show high growth associated with economic development (14).

Together with the high incidence of CRC and other intestinal diseases that lead to intestinal surgery, this surgical technique is also greatly progressing. Thus, and with the aim of minimizing the side effects of this intervention, anterior resection with preservation of sphincter function is the treatment of choice (15). Anastomotic leakage is one of the most feared complications after CRC surgery. It occurs in approximately 5% of patients following potentially curative resection and is more common in those undergoing rectal surgery, those with a low anastomosis (16). It has been observed that the completion of a temporary stoma is effective in reducing anastomotic leakage rates and reoperation rates after previous resection in patients with rectal cancer (15,16). In those cases, the patients lose the function of the sphincter, some permanently and others temporarily. But in those cases, patients experience a strong change in their lives that translates into a great psychological impact.

Within the areas of life that are affected in enterostomy carriers and that seriously affect their perception of quality of life, these patients also require an important behavioral change in daily routines, as well as inclusion in life daily of behaviours towards personal care and hygiene that require a lot of time and dedication (17–19).

The first change caused by enterostomy is that it requires the acquisition of knowledge and psychomotor skills needed to manage an ostomy (19–22). These changes involve selection, application and removal of a pouching system, caring for the peristomal skin, learning how to empty its pouching system, and learning the effects of various foods and beverages on the volume and consistency of fecal effluent. The patient's ability to care for their ostomy is termed self-care (SC), defined by Orem, Taylor and Renpenning as "the practice of learned actions, directed towards oneself or towards the environment, to regulate the factors that affect their own functioning or development for the benefit of their life, health or well-being" (23). SC is considered essential in the management of chronic illness (24) and has been considered as a possible way to achieve positive health outcomes related to psychological adjustment in patients with a colostomy (25). A successful adjustment to the permanent colostomy is more probably when the patient is adequately instructed in self-care (26).

In chronic diseases such as the one we are dealing with, and in being a carrier of an elimination enterostomy, one of the health indicators that acquires special importance is the HRQOL, since it provides us with the perception that the patient has on his/her own health, that is, on his/her physical, psychological, and social limitations and on diminishing opportunities due to the disease, its sequelae and treatment (27). The measurement of the HRQOL becomes the main indicator of health and adjustment to the disease in patients with a chronic illness or chronic condition such as being a carrier of an enterostomy (28,29).

With the referenced antecedents, we consider it of great interest to investigate the relationships between Stoma SC, clinical and sociodemographic variables and HRQOL of ostomates. These aspects can be essential for the nursing professionals responsible for caring for these patients.

2. Materials and Methods

The primary purpose of this study was to assess stoma SC and HRQOL in patients with drainage enterostomy, describe clinical and sociodemographic variables and analyze the correlations between all of them.

We hypothesized that:

1. Stoma SC in patients with drainage enterostomy would be poor.

2. Some domains of both stoma SC would be associated with HRQOL in patients with drainage enterostomy.

3. Some ostomy-related sociodemographic and clinical characteristics would be correlated with stoma SC in patients with drainage enterostomy.

This was a multicenter, cross sectional study conducted in four hospitals of the public health system of the province of Castellon, Spain, who had a colorectal surgery service and a stoma nursing unit. The study was classified by the Spanish Agency for Medicines and Healthcare Products (Agencia Española de Medicamentos y Productos Sanitarios), which belongs to the Ministry of Healthcare, Social Services and Equality, as a "Nonpost authorization observational study". Potential participants were drawn from these 4 hospitals. Study procedures were reviewed and approved by the 4 hospitals' research ethics committees. Care was taken to ensure subjects' privacy; subjects were assigned a deidentified study number and all data are based on analysis of an aggregate. Respondents provided informed consent before participating.

To estimate the sample size for these evaluations, we used findings from Liu and colleagues (30), who reported a stomal and peristomal incidence rate of 14% in a group of 796 patients following stoma surgery. To obtain a precision of 3.5% in the estimation of a proportion by means of a normal asymptotic confidence interval with correction for finite populations at 95% bilateral, we estimated a minimum sample size of 117 participants. We anticipated a 10% dropout rate and elected to recruit 139 subjects. Sample size estimates were generated using the Sample Size Estimation Software, version 3.0 (Vanderbilt University Biostatistics, Nashville, Tennessee).

Inclusion criteria were (1) performance of a colostomy or ileostomy 3 months or more prior to study enrollment, (2) being older than 18 years of age, (3) being capable of speaking, (4) writing, and (5) understanding Spanish, and (6) being cognitively able to provide informed consent. Individuals undergoing palliative stoma surgery as part of endof- life care were excluded from participation.

Participating facilities were the General Hospital of Castellon (574 beds with 12.529 surgical procedures completed in 2015), Provincial Hospital of Castellón (263 beds and 6702 surgical procedures completed in 2015), Vila-Real Hospital (258 beds and 8.764 surgical procedures completed in 2015), and Vinaroz Hospital (139 beds and 4.983 surgical procedures completed in 2015). From these facilities, we identified 185 patients who underwent ostomy surgery and could be contacted for potential study participation. Sixty (32.4%) were eliminated based on failure to meet inclusion/exclusion criteria, and the remaining 125 (67.6%) individuals consented to participate in the study.3

The protocol, which was developed by a multidisciplinary team that included nurses and physicians, was created for the use of critical care RNs practicing in the colostomy office by trained interviewers. Administration of questionnaires and collection of information were coordinated by the Universitat Jaume I of Castellón (Spain).

Data were collected during a period of 12 months, from January 2016 to January 2017. Data were extracted and maintained in an SPSS spreadsheet in a deidentified format using a standardized form. Administration of questionnaires and collection of information were coordinated by the Universitat Jaume I of Castellón (Spain). Trained interviewers collected data using a standardized form that queried sociodemographic

characteristics. Pertinent clinical data were obtained from the review of the electronic medical record.

The variables collected were the following:

Socio-demographic and medical characteristics

Sociodemographic characteristics included sex, age, education level, marital status, place of residence, living status, primary caregiver, occupation, and monthly family income. Ostomy-related clinical characteristics queried included type of ostomy (ileocolostomy or colostomy), date ostomy was created, medical diagnosis leading to ostomy creation, temporality of the ostomy (temporary vs permanent), stoma level with respect to the adjacent abdominal wall, use of irrigation, autonomy in ostomy care.

The Specific Self-Care for Ostomized Patients Questionnaire (CAESPO)

The CAESPO (31) comprises of 3 main subscales: 21 items query general SC, 18 items query personal development and social interaction SC (development SC), and 18 items query aspects of specific SC related to the presence of an ostomy (specific SC). Each subscale assesses knowledge, practical dimension and degree of interest in SC, as indicated in Orem's theory of the 3 SC domains (knowledge of SC, interest and attitude toward SC, and SC behaviors). Items are scored using an ordinal scale of 1 (low level of SC) to 4 (high level of SC). The CAESPO score varies from 58 to 232 points, which is converted to an adjusted scale of 0 to 100; higher scores indicate higher levels of selfcare.

The Stoma Quality of Life (S-QoL).

The S-QoL (32) contains 2 factors—stoma care subescale and social subescale—covered in 28 items. Respondents choose 1 of the 5 possible answers, ranging from "not at all confident" to "extremely confident". Higher scores correspond to higher levels of confidence.

Validity and reliability / Rigour

All the measuring instruments used have shown adequate reliability and validity. More specifically, the internal consistency of the CAESPO score was good ($\alpha = 0.889$) and Test-retest reliability was excellent ($\alpha = 0.987$); the Construct Validity indices obtained by SEM are adequate ($\chi^2 = 43.132$, $p < .001$; RMSEA = 0.155 [0.107-0.204]; BBNFI = 0.957; CFI = 0.967; IFI = 0.968). Cronbach α values for the CAESPO subscales were: general SC (α = .754), development SC($\alpha = 0.786$), and specific SC ($\alpha = 0.908$) (31); and Cronbach α values for the S-QoL total score, stoma care SE, and social SE were 0.97, 0.97, and 0.89 in the original study (32).

Data were analyzed using the Statistical Package for the Social Sciences software versión 23.0 (SPSS, Chicago, Illinois). All statistical tests were 2-tailed, and the threshold for statistical significance was an α level of less than 0.05. Appropriate descriptive statistics, including mean (standard deviation, SD) and frequency (percentage), were used to summarize and present the data. All variables were first screened for their normality assumption using Kolmogorov-Smirnov test. A Spearman correlation analysis was used to investigate the correlation between each subescales of CAESPO and S-QoL, and due their non-normality. Independent Mann-Whitney U and Kruskal-Wallis tests were used to explore the differences in the scores of both questionnaires and their subscales according to sociodemographic or clinical data.

3. Results

Of the total number of 139 subjects, 14 subjects did not complete the questionnaires and 5 were eliminated for having extreme values, resulting in the final sample of 120 subjects. The mean age of the 120 subjects taking part in this study was 66.91 years (SD: 11.82), and the mean length of time since the placement of the stoma was 1379.9 days (SD:

1227.32). Most of the participants were males (64.2%, n: 77), married (83.3%, n: 100), retired (75.8%, n: 91), autonomous in their care (79.8%, n: 95), with primary studies (45%, n: 54) and with an annual income of less than 6.000€ (64.17%, n: 77). With regard to the clinical characteristics of the participants, most of them did not report any complications related to the stoma (84.7%, n: 100), the majority of them being colostomies (81.7%, n: 98), permanent (65%, n: 78), and, in most cases, using one-piece closed collection systems (40.8%, n: 49). A more detailed breakdown of these socio-demographic variables can be observed in Table 1.

Table 1: Characteristics of the subjects included in the study.

Socio-demographic		
Mean age, in years ± SD		66.91 ± 11.82
Median nº children [min, max]		2 [0, 7]
Sex	Women	43 (35.8%)
Marital Status	Single	6 (5%)
	Married	100 (83.3%)
	Separated - Divorced	2 (1.7%)
	Widow/er	12 (10%)
Estudios	None	33 (27.5%)
	Basic	54 (45%)
	Secondary school – Voc. Tr.	22 (18.3%)
	University	11 (9.2%)
Employment Status	Retired	91 (75.8%)
	Employee / Self-employed	14 (11.7%)
	Others	15 (12.5%)
Clinical		
Mean nº days with the Stoma		1379.9 ± 1227.32
Type of ostomy	Colostomy	98 (81.7%)
	Ileostomy	22 (18.3%)
Autonomous in their care	Yes	95 (79.8%)
Complications	No Complications	100 (84.7%)
	Stenosis	11 (9.3%)
	Oedema	1 (0.8%)
	Prolapse	3 (2.5%)
	Retraction	1 (0.8%)
	Pain	2 (1.7%)
Type of Appliance	Piece with no tap	49 (40.8%)
	Piece with a tap	26 (21.7%)
	Pieces with no tap	23 (19.2%)
	Pieces with a tap	22 (18.3%)
Appliance time frame	Permanent	78 (65%)
Stoma level	Invaginated	7 (5.8%)
	Flush	48 (40%)
	Protruding	65 (54.2%)

Table 2 presents the average scores obtained in the different subscales of the instruments used, together with their normality tests. It is observed that all scores, both average and median, of the subscales yielded values above 50%. The only scores that followed a normal distribution were STOMA quality of life global score and STOMA quality of life personal subscale (marked with "*" in Table 2).

Table 2: Descriptive statistics of Questionnaires

	Mean	Median	SD	Min	Max	K-S	p
CAESPO General Self Care	70.82	72.77	9.42	45.56	92.78	.134	.000
CAESPO Developmental Self Care	74.32	73.88	7.96	46.39	94.72	.128	.000
CAESPO Specific Self Care	74.42	72.91	10.91	46.34	100	.128	.000
STOMA QOL Global	80.94	72.5	12.46	51.25	100	.079	.066*
STOMA QOL F1 (Personal)	73.85	90	15.67	40	100	.081	.053*
STOMA QOL F2 (Social)	88.00	66.67	12.38	47.50	100	.166	.000

Given the non-normality of the scores, a Spearman's Rho correlation analysis was carried out between the scores of the different dimensions of the instruments used, observing that there was a significant correlation between the STOMA quality of life scores among the general SC knowledge and general SC practice (Table 3).

Table 3. Spearman Correlation

CAESPO General Score	ρ	.227*	.366**
	p	.011	.000
	N	124	125
CAESPO Developmental Score	ρ	-.051	.067
	p	.572	.456
	N	124	125
CAESPO Specific Score	ρ	-.059	-.006
	p	.519	.949
	N	124	125

Regarding the sociodemographic variables, significant differences were found according to sex, based on the Mann-Whitney U test, in the CAESPO general SC score ($U_{M\text{-}W}$ = 32227.50, p = .043), with the highest score being observed in women. No differences according to sex were observed for any of the other variables (p > .05).

In relation to marital status, and according to the Kruskal-Wallis test, significant differences were found for the CAESPO development SC score (χ^2 = 12.022, p = .007), and for the social dimension of Stoma QOL (χ^2 = 11.292, p < .010), where married participants show a higher score than the rest. Significant differences according to work activity were also observed for CAESPO development SC scores (χ^2 = 10.986, p < .010), and the CAESPO specific SC scores (χ^2 = 23.173, p < .010), with those employed obtaining higher scores. No significant differences were observed for any of the SC scores studied according to the level of studies across the two instruments (p > .05).

Regarding the clinical variables, differences between groups were observed according to the autonomy of care, the presence of complications in the stoma, the use of irrigation and the type of effluent. According to the autonomy of the subjects in relation to the care and management of the stoma, there were significant differences in all self-care factors, CAESPO general SC scores ($U_{M\text{-}W}$ = 861,50, Z = -2.343, p = .011), CAESPO developmental

SC scores ($U_{M\text{-}W}$ = 800.5, Z = -2.839, p < .010) and, CAESPO specific SC scores ($U_{M\text{-}W}$ = 809,50 Z = -2.668, p = .008), with those subject who are autonomous in their care obtaining higher scores.

Considering the complications of the stoma, significant differences in the Stoma QOL Personal factor scores ($U_{M\text{-}W}$ = 737, Z = -2.062, p = .039), and in the Stoma QOL Social factor scores ($U_{M\text{-}W}$ = 532.5, Z = -3.534, p < .01) were found. And with respect to Caespo, significant differences with respect to the general SC scores ($U_{M\text{-}W}$ = 728.5, Z = - 2.166, p = .030) were found, with those patients with complications in the stoma obtaining a worse quality of life and a worse level of self-care.

Regarding the use of irrigations through the stoma as a control measure of intestinal effluents, differences in the level of self-care measured with CAESPO were observed, both in the developmental SC score ($U_{M\text{-}W}$ = 655.5, Z = -2.885, p = .004), and in the specific SC score ($U_{M\text{-}W}$ = 614, Z = -3.167, p = .002), with patients who perform irrigation obtaining a higher level of self-care.

In relation to Effluents, and according to self-care and CAESPO scores, significant differences with respect to general SC Score ($H_{K\text{-}W}$ = 10.432, p = .015) were obtained, not finding differences in Effluents for both the developmental sSC score ($H_{K\text{-}W}$ = 1.605, p = .658), and the specific SC score ($H_{K\text{-}W}$ = 1.938, p = .585).

No significant differences were observed (p > .05) between groups considering the following variables: type of ostomy, temporality of the stoma, or the type of drainage device used.

4. Discussion

Our analyses show that self-care has a direct relationship on the well-being and health of patients with an enterostomy, revealing self-care as a predictor of quality of life, both in relation to social and personal factors. This information is in clear consonance with the conclusions of other research conducted on self-care and quality of life in ostomized patients (25,26,33–37). The same phenomenon has been previously analyzed in other chronic diseases (38).

Female patients scored higher on the General SC Knowledge subscale than male patients. Similarly, patients who live as a couple also showed significantly higher values in the CAESPO Developmental SC Practice, Stoma QOL and Social dimension of Stoma QOL compared to those who do not. Our results contrast with previously published studies that have found that women and married patients can deal better with CRC than men and unmarried patients (35,39). Probably, the average age of the sample and sociocultural factors, such as employment activity, can justify this association.

In relation to the clinical variables, we found that patients with some type of complication related to the stoma showed differences in the level of quality of life, which was reduced. This association coincides with the findings of other studies (4,37,40) and highlights the great importance of the stoma therapist's role after colorectal surgery in the therapeutic education of these patients. It is essential to acquire knowledge and skills for the adequate care of the periostomal skin, the use of drainage devices and the management of possible complications, which will derive in greater autonomy (41). Our findings coincide with those of other authors (25), in which those patients who are autonomous and can clean and change their ostomy pouch by themselves present a higher level of self-care and a higher quality of life.

Other clinical variables that have been shown to be associated with SC are irrigations and type of effluent. Colostomy irrigation involves irrigating the colon regularly to establish a regular bowel habit (42). Other previous studies have already inquired about the role of colostomy irrigation in the quality of life of patients (43,44). In our patients, those patients who used irrigation as a method of controlling fecal waste, showed a higher level of significant self-care in the CAESPO development and specific score,

showing greater involvement in all aspects related to the control of their process, although they did not show a higher level of quality of life than the rest.

Contrary to the findings of other authors (36,45), we have not found differences in the level of self-care or quality of life depending on the type of ostomy. However, we have found differences according to the type of effluent. The stool of patients with ileostomy is usually pasty or even fluid, which facilitates the appearance of periostomal lesions due to the moisture over the skin and the acidity of the stool (46). We have found a higher level of self-care among those patients with stool with pasty consistency versus those with normal or hard consistencies. Similarly, these patients have shown higher levels of quality of life, which is a finding consistent with Magistri et al.'s results (45).

From the findings presented, it is necessary to highlight the relationship between the level of self-care and the quality of life of ostomized patients. In this aspect, the role of the stoma therapist is fundamental. It is necessary to consider in the care of these patients that the influence of some clinical variables such as complications related to the stoma or the characteristics of the stool, as predictors of a poor quality of life.

Our study approaches the problem, in an original and novel way, from a nursing theoretical framework based on the self-care model. Given that it is the first time that the Specific CAESPO self-care questionnaire has been used, it is not possible to compare it with other samples or to determine the exact level of self-care of the studied population. However, given that the different factors and dimensions of self-care yielded scores that exceeded, in general, the average established in the validation of the instrument (31), it can be considered that the level of acquisition of competences in Self-care by the studied population was high, although it could be improved in some aspects.

The level of self-care in patients with ostomies has been studied, using other instruments, in previous studies. Thus, it is noteworthy that the present study's results are similar and comparable to those of Knowles and colleagues (47) with a sample of colostomized Australian patients and to those obtained by Wu et al. (37), in a sample of 96 stoma patients in Hong Kong. As in our results, both studies show a high level of self-care in ostomized patients. However, our results differ from those presented by Su and colleagues (40), which were considerably poorer, perhaps conditioned by being exclusively patients with temporary ostomies. Other studies have shown the temporality of the type of stoma as a conditioning factor, compared to stoma acceptance and stoma care self-efficacy (4), although our results do not indicate significant differences in the stoma temporality.

5. Conclusions

In the present study, we attempted to examine the level of SC and its relation to QOL in a sample of 120 Spanish patients with an elimination enterostomy.

We found that the stoma SC level was high and was positively correlated with the QOL of these patients. Sociodemographic variables including gender, marital status and economic income were also associated with the level of stoma SC. The clinical variables associated with the level of SC were the presence of complications related to the stoma, the type of effluent and the use (or not) of regular irrigations of the colon.

Based on the results of this study, we can highlight the great importance that the acquisition of a high level of skills related to SC by ostomized patients has for a good level of HRQOL. The health services must provide patients with the necessary tools for their acquisition and, in this learning process, the figure of the stoma therapist plays a very important role.

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