Technological innovation to colostomy bags: quasi-experimental study

Inovação tecnológica à bolsa de colostomia: estudo quase-experimental

Innovación tecnológica a la bolsa de colostomía: estudio cuasi-experimental

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ABSTRACT

Objective: To verify the effect of the bag with irrigation valve on the pattern of (dis)comfort of the colostomy person.

Method: Quasi-experimental study, with a single group, through pre and post-test, carried out from June to September/2020 with 33 colostomized patients from a municipal rehabilitation center in Rio de Janeiro, Brazil. The pattern of (dis)comfort was analyzed using fuzzy logic, considering the attributes of bag cleaning, gas elimination and odor control.

Results: When analyzing the difficulty presented in each attribute before (T_0) and after intervention (T_1), a reduction was observed in relation to "bag cleaning" for 17 (56.7%) participants, in "odor control", for 24 (80.0%) and "gas removal" for 16 (53.3%) participants. By crossing the three attributes at the two moments, 21 (69.9%) participants indicated a reduction in (dis)comfort at T_1.

Conclusion: There was a reduction in the pattern of discomfort with the use of the bag with irrigation valve compared to the traditional colostomy bag.

Keywords: Nursing. Ostomy. Colostomy. Colonic pouches. Biomedical technology.

RESUMO

Objetivo: Verificar o efeito da bolsa com válvula de irrigação no padrão de (des)conforto da pessoa colostomizada.

Método: Estudo quase-experimental, com grupo único, mediante pré e pós-teste, realizado de junho a setembro/2020 com 33 colostomizados de um centro municipal de reabilitação do Rio de Janeiro, Brasil. Analisou-se o padrão de (des)conforto mediante a lógica *fuzzy*, considerando os atributos de limpeza da bolsa, eliminação de gases e controle do odor.

Resultados: Ao analisar a dificuldade apresentada em cada atributo antes (T_0) e após intervenção (T_1), constatou-se redução em relação a "limpeza da bolsa" para 17 (56,7%) participantes; no "controle do odor", para 24 (80,0%) e "retirada de gases" para 16 (53,3%) participantes. Mediante cruzamento dos três atributos nos dois momentos, 21 (69,9%) participantes indicaram redução do (des)conforto em T_1.

Conclusão: Constatou-se redução no padrão de desconforto com o uso da bolsa com válvula de irrigação comparado à bolsa de colostomia tradicional.

Palavras-chave: Enfermagem. Estomia. Colostomia. Bolsas cólicas. Tecnologia biomédica.

RESUMEN

Objetivo: Verificar el efecto de la bolsa con válvula de irrigación sobre el patrón de (in)comodidad de la persona colostomizada.

Método: Estudio cuasi-experimental, con un solo grupo, a través de pre y post-test, realizado de junio a septiembre/2020 con 33 pacientes de colostomía de un centro de rehabilitación municipal de Río de Janeiro, Brasil. El patrón de (des)confort se analizó mediante *fuzzy* logic, considerando los atributos de limpieza de bolsas, eliminación de gases y control de olores.

Resultados: Al analizar la dificultad presentada en cada atributo antes (T_0) y después de la intervención (T_1), se observó una reducción en relación a "limpiar la bolsa" para 17 (56,7%) participantes; en "control de olores", para 24 (80,0%) y "eliminación de gases" para 16 (53,3%) participantes. Al cruzar los tres atributos en los dos momentos, 21 (69,9%) participantes indicaron una reducción de la (des)comodidad en T_1.

Conclusión: Hubo una reducción en el patrón de malestar con el uso de la bolsa con válvula de irrigación en comparación con la bolsa de colostomía tradicional.

Palabras clave: Enfermería. Estomía. Colostomía. Reservorios cólicos. Tecnología biomédica.

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■ INTRODUCTION

The estimate of cancer in Brazil, triennium 2020-2022, will reach 625 thousand new cases, of which 41 thousand will be colon and rectal cancer, resulting in the second most prevalent in the adult population[1]. With these increasing rates, the manufacture of intestinal stomas has increased significantly. According to the International Ostomy Association, in developed countries, there is about one ostomized patient for every 1,000 inhabitants, however this number can be quite high in less developed nations.

In addition to colorectal cancer, obstructions, inflammatory diseases and intestinal trauma, lead to the need for surgical intervention that often also result in stoma creation[2]. This is characterized by a new pathway of the colon or ileum through the abdominal wall, creating an artificial opening to take out fecal content, which can be temporary or permanent, depending on the degree of organ impaired[3].

In addition to changes in self-image and self-esteem, stoma creation, whether temporary or permanent, imposes on the person with a stoma the need to adapt to this new condition, including daily management of the stoma, which can also negatively reflect on the emotional and social spheres. Among the main difficulties faced in daily life, cleaning the collection bag, the accumulation of gases, and the elimination of odors stand out[4]. Finding ways to ease adaptation and soften the effects of this new reality becomes crucial[4,5].

In this context, the nurse has a fundamental role[6,7], not only in the educational aspect, but also in the sense of proposing technological innovations that ease the adaptation of the person to the changes imposed by the stoma creation. In view of the above, aiming at facilitate the handling of the bag and consequently reduce the discomfort of the ostomized patient during bag cleaning, gas elimination and odor control, an irrigation valve was designed to be attached to the colostomy bag. As it is an innovative technological product, it is important to mention that the deposit was made with the National Institute of Industrial Property (*Instituto Nacional da Propriedade Industrial* – INPI), patent application No. BR 20 2018 014936 4.

Thus, the following research question arose: what is the effect of using a colostomy bag with irrigation valve on the pattern of (dis)comfort of the colostomized person? In this way, the study aims to verify the effect of the colostomy bag with irrigation valve on the (dis)comfort pattern of the colostomized person.

■ METHOD

Type of study

This is a quasi-experimental study, from a Professional Master's dissertation in Nursing Care, conducted with a single group, evaluated before (T_0) and after intervention (T_1). Considering the subjectivity involved in differentiating the (dis)comfort pattern of the ostomized person, it was necessary to adopt a method that extrapolates dichotomies (yes/no, true/false) normally used in quantitative studies. Thus, it was decided to treat the data using fuzzy logic, which breaks with the limitations of this binary quantification, characterizing a quali-quantitative study[8].

The fuzzy logic, based on the fuzzy set theory, has been gaining ground in various fields of science[9]. It was developed in 1965 by Lotfi Asker Zadeh, an electronic engineer and professor at the University of California – Berkeley. Fuzzy logic is defined as the one that approaches the human mind with the ability to encode ambiguous information, whose limits do not have clear borders, in addition to defining the degree of importance to each element, unlike very rigid mathematical theories[9,10]. Considering that many human experiences cannot be simply categorized as true or false, and impossible to define whether the element belongs or does not belong to a certain set, Zadeh suggested the use of the degree of pertinence, considering that an element may partially belong to a certain set. Thus, the degree of pertinence of the different elements in the set must be considered, allowing them to be classified and grouped differently from classical logic, working with values of truth that range between completely true and completely false referring to Boolean logic, making it possible to work with linguistic variables[9,10].

To obtain the fuzzy sets, it is necessary to generalize the characteristic function of classical logic to the interval [0,1], considering a continued pertinence value and not just the extreme values zero and one. Thus, a linguistic variable is expressed by a linguistic term, which assigns a classification to the variable, and quantitatively by a pertinence function[9,10].

Fuzzy sets allow the graphic visualization of linguistic variables, without defined boundaries[10,11]. These are represented by geometric figures, in the case of this study it was opted trapezoids with a support consisting of a chromatic scale.

The use of fuzzy logic was also justified by the reduced sample of participants, since a statistical inferential method

would be compromised in credibility, since the results would not converge to the probability distributions used in the hypothesis tests.

Population and sample

The research was conducted with colostomized people followed up at the municipal rehabilitation center, a health unit linked to the Municipal Health Department of Rio de Janeiro, Brazil, a reference in rehabilitation in auditory, physical, intellectual, and visual specialties of a permanent or temporary nature.

The selection of participants was conducted in an institution file, organized by records in alphabetical order, meeting the following inclusion criteria: over 18 years old, with permanent colostomy on the left, using a one-piece collection bag. As exclusion criteria, continuous use of the traditional bag for less than three months was considered; complications at the stoma site; use of irrigation and stoma occlusion; residing outside the Municipality of Rio de Janeiro or in an area of risk, that is, with a history of high level of violence; lack of complete data in the patient's record. Thus, based on the established criteria, 98 probable participants were listed, which corresponded to the size of the study population.

Sampling without replacement should be adopted to estimate the prevalence of colostomized patients in the population, adopting an estimate error of 10% and a probability of reliability of 95 chances out of 100, which would lead to a sample of 48 participants. However, it is worth highlight that when trying to make the first telephone contact with the probable 98 participants, 32 were unsuccessful, as they did not answer or had their number changed; 29 refused the home assessment, remaining 37 who, after receiving initial guidance on the research, provided authorization for the home visit, scheduled according to their availability. Considering that the contacts were made at the Covid-19 pandemic, there was resistance to home visits by some participants, even after guidance on the implementation of prevention measures by the researcher.

Upon arriving at the home of the probable participants who accepted the visit, their eligibility was confirmed, with 04 being excluded for not meeting the established criteria due to complications at the stoma site. After receiving the information about the research, voluntary agreement and signing the Free and Informed Consent Form (FICF), 33 remained, but 03 gave up during the research, remaining 30 participants. This fact does not invalidate the research, since the method was chosen with the use of fuzzy sets that infer pertinence referring to the assessed attributes and not estimates of prevalence according to categories.

Data collection

It was conducted from June to September 2020, and the form was applied to data collection, such as: reason for making the colostomy, time of colostomy, type of bag used. In addition, it was performed the first evaluation of the (dis)comfort with the use of the traditional colostomy bag (T_0), considering the difficulties presented regarding the attributes: "bag cleaning", "gas removal" and "odor control".

The evaluation of each attribute by the participant occurred through the application of a chromatic scale[11] (Figure 1) considering that the warmer the color, the greater the difficulty, which would constitute the support of the linguistic variables of the trapezoidal fuzzy sets. On the back of this scale the date, participant identification, moment (T_0 or T_1) and the corresponding linguistic attribute were recorded.

Thus, in the first home visit, to identify the pattern of (dis)comfort before the intervention (T_0), each participant marked on the scale the color corresponding to the intensity of the difficulty related to each attribute with the use of the traditional bag. After the evaluation (T_0), a colostomy bag was provided with the same characteristics as the one used by the participant, including only the irrigation valve and the participants were trained/qualified to use the device, in addition received an instruction manual, in order to clarify any doubts during use.

The evaluation of the same attributes to investigate the pattern of (dis)comfort of the participants using the bag
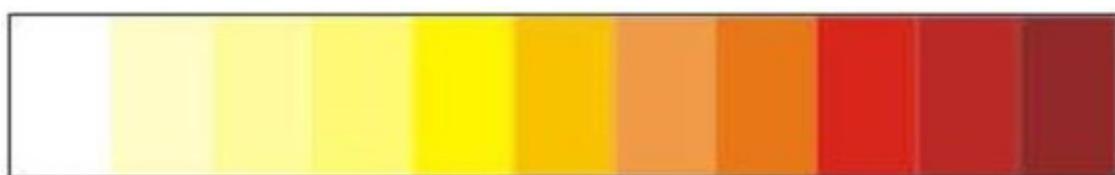

Figure 1 – Chromatic scale. Niterói, Rio de Janeiro, Brazil, 2020
Source: Brandão, Santos, Lanzillotti, 2012[11].

with irrigation valve (T_1) occurred after seven days, and all received three bags with irrigation valve, and 01 syringe of 60 ml with luer lock spout and plastic lid. It is highlighted that in T_0 and T_1, the same trapezoidal fuzzy sets were applied with the respective linguistic variables having as support the chromatic scale to evaluate the difficulty related to the three attributes: "bag cleaning", "gas removal" and "odor control".

Data analysis

The determination of the linguistic variables resulting from the fuzzy system followed the criteria of a previous study conducted to evaluate an intervention with people with pemphigus vulgaris[11]. Considering that a fuzzy linguistic variable is expressed by a linguistic term, which gives a concept to the variable, and quantitatively by a pertinence function[12], in this study the following linguistic variables were used: minimum, slightly moderate, moderate, moderately maximumdifficulty and maximum, passing through and quantifying the degree of difficulty by the pertinence by classification. The pertinence calculation was obtained as a function of the equations of the lines inherent to the trapezoids, including at the intersection of trapezoidal sets, the minimum pertinence and the respective category of the linguistic variable were adopted.

Thus, fuzzy logic enabled the survey of different degrees of pertinence, consisting of a tool that can capture vague information, converting them into easily understandable values of pertinence in the ratio scale (Fuzzification)[12]. The fuzzy sets allowed to identify the difficulties as: maximum; moderately maximum; moderate; slightly moderate; minimum) and obtain the membership values for each attribute at times T_0 and T_1. The visualization of trapezoidal fuzzy sets supported by the chromatic scale and respective fuzzy linguistic variables are shown in Figure 2.

After the "fuzzification", obtaining the linguistic variables and their respective pertinence, the fuzzy rules "If... then" were established, like an "inference machine" to extract categorical scenarios of discomfort[13], which in this experiment resulted in 14 (fourteen) rules and five possibilities of (dis)comfort pattern before and after the intervention, as shown in Figure 3. Thus, the fuzzy inference machine defined the linguistic categorical scenarios for moments T_0 and T_1, being calculated the weighted average pertinence, considering the weights three, two and one for the attributes "bag cleaning", "odor control" and "gas removal", respectively, hierarchically based on the strength that each one represents in the pattern of discomfort experienced by the participant.

The fuzzy system is designed according to input variables that allow categorizing them and obtaining the respective pertinence according to the fuzzy sets. The fuzzy inference machine allows the interaction between input variables (antecedents) with output variables (consequences), describing situations whose inference leads to a result. In this study, the measurement corresponds to the effect of a technology on the pattern of (dis)comfort. This logical system was developed by nurses experts in stomatherapy and dermatology, aiming to translate the interaction between attributes considered relevant for the assessment of (dis)comfort.
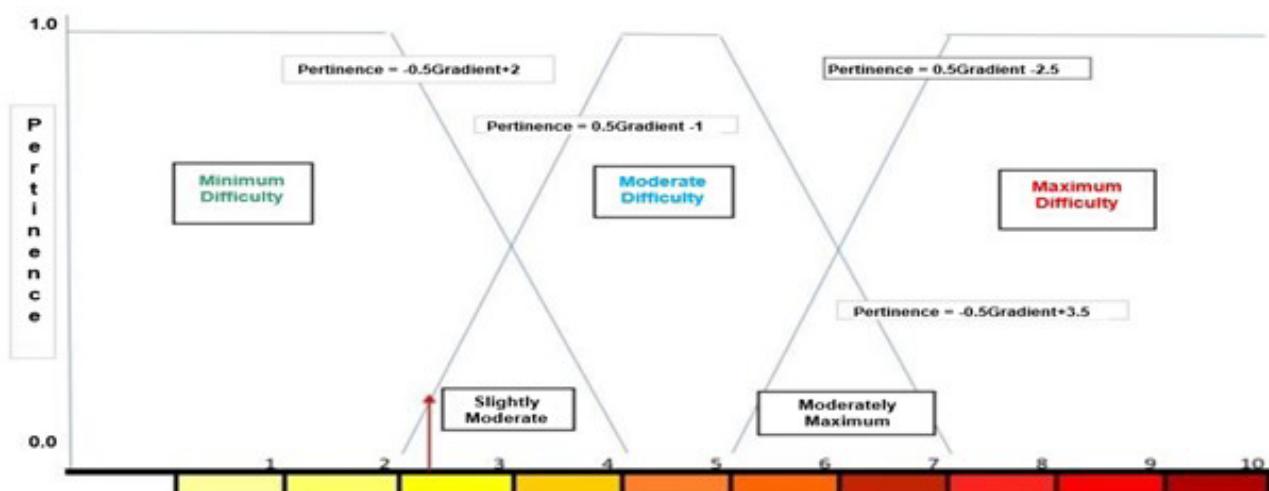

Figure 2 – Chart of trapezoidal fuzzy sets regarding the linguistic terms of difficulties and equations of the lines pertinent to the edges to obtain the pertinence. Niterói, Rio de Janeiro, Brazil, 2020
Source: Research data.
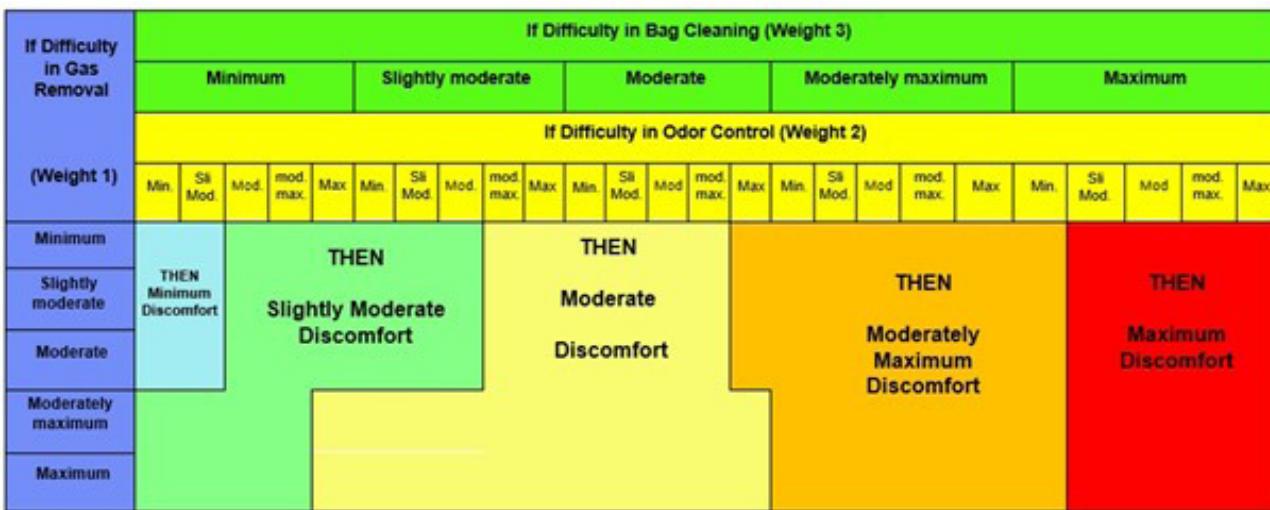
Figure 3 – Fuzzy machine to determine (dis)comfort (consequent) according to linguistic terms inferred by the attributes "gas removal", "odor control" and "bag cleaning", attributing weightings 1, 2 and 3 respectively. Niterói, Rio de Janeiro, Brazil, 2020
Source: Research data.

The comparison of the results allowed to verify the occurrence or not of migration between linguistic variables, pointing out their respective pertinence. Thus, it made it possible to infer whether there was a migration of category and/or pertinence within the same category, that is, if there was a change in the pattern of (dis)comfort with the use of the irrigation valve.

Ethical aspects

The research was conducted after approval by the Research Ethics Committee of the Faculty of Medicine of the *Universidade Federal Fluminense*, according to CAAE 17566319.5.0000.5243, and opinion No.4,463,160/2020 of the Municipal Health Department of Rio de Janeiro.

■ **RESULTS**

Among the 30 participants, there was a predominance of males, aged over 60 years, white ethnicity, married marital status, who went to elementary school, retired and living with one to two people in the same household. The education level ranged between complete elementary school, with eight (26.6%) and complete higher education, with seven (23.3%) participants.

Regarding the clinical characteristics, it was observed that 23 (76.6%) participants were diagnosed with cancer, being 13 (43.3) rectal and ten (33.3) of the colon; 11 (36.7%)

underwent colostomy between one and two years; 09 (30%) between three and four years. The opaque bag without a filter was predominant among the participants 11 (36.7%).

Regarding the evaluation of the difficulty presented in each attribute and the respective pattern of discomfort before(T_0) and after the intervention(T_1), when observing Tables 1 and 2, it is noticed in relation to "bag cleaning", that 17 (56 .7%) participants migrated positively after using the bag with irrigation valve. However, six (20.0%) maintained the pattern of (dis)comfort. In the attribute "odor control", which is closely linked to the other attributes, the use of a bag with a valve reduced discomfort for 24 (80.0%) participants and five (16.6%) maintained the pattern of (dis)comfort. Regarding the attribute "gas removal", although the reduction in discomfort was less expressive, 16 (53.3%) participants showed a reduction and only one (3.3%) maintained the pattern of (dis)comfort.

By assigning weights, weights 1, 2 and 3 to the attributes "gas removal", "odor control" and "bag cleaning", respectively, it was possible to obtain the weighted average pertinence for each study participant, column 9 of Tables 1 and 2.

Table 3 shows the pattern of (dis)comfort and the respective weighted average pertinence at moments T_0 and T_1. It is observed that there was positive migration or increase in weighted average pertinence for 21 (69.9%) and negative migration or reduction of these pertinence for nine (31.1%) participants.

Table 1 – Difficulty and (dis)comfort pattern of the participants in linguistic terms and respective pertinence with the use of the traditional bag, according to the attributes bag cleaning, odor control and gas removal at momentT_0. Niterói, Rio de Janeiro, Brazil, 2020

P	Difficulty at momentT_0						Discomfort Pattern at moment T_0	
	Bag cleaning (W3)	Pert	Odor control (W2)	Pert	Gas removal (W1)	Pert	Result	Weighted Pert
2	Maximum	1.00	Maximum	0.28	Maximum	1.00	Maximum	0.76
4	Maximum	1.00	Maximum	0.19	Maximum	1.00	Maximum	0.73
5	Maximum	1.00	Maximum	0.22	Maximum	1.00	Maximum	0.74
6	Maximum	1.00	Maximum	1.00	Maximum	1.00	Maximum	1.00
7	MM	0.22	Maximum	0.24	MM	0.19	MM	0.22
8	Maximum	1.00	Maximum	1.00	Maximum	1.00	Maximum	1.00
9	Maximum	1.00	Maximum	0.22	Maximum	1.00	Maximum	0.74
10	Moderate	1.00	Maximum	1.00	Moderate	1.00	MM	1.00
11	MM	0.28	MM	1.00	MM	0.27	MM	0.52
12	Maximum	1.00	Maximum	1.00	SM	0.25	Maximum	0.88
13	MM	0.22	Maximum	0.22	MM	0.30	MM	0.23
14	Maximum	1.00	Maximum	1.00	SM	0.25	Maximum	0.88
15	Maximum	1.00	Maximum	0.24	SM	0.25	Maximum	0.62
16	MM	0.27	Maximum	1.00	MM	0.22	MM	0.51
17	SM	0.28	Maximum	1.00	SM	0.25	Moderate	0.52
18	Moderate	1.00	Maximum	0.25	Moderate	1.00	MM	0.75
19	Moderate	1.00	Maximum	0.09	Moderate	1.00	MM	0.70
20	SM	0.06	Maximum	0.06	SM	0.13	Moderate	0.07
21	Moderate	1.00	Maximum	0.09	Moderate	1.00	MM	0.70
22	MM	0.31	Maximum	0.22	Moderate	1.00	MM	0.40
24	Maximum	1.00	Maximum	1.00	SM	0.38	Maximum	0.90
25	Moderate	1.00	Maximum	0.35	SM	0.09	MM	0.63
26	MM	0.25	Maximum	0.09	MM	0.25	MM	0.20
27	MM	0.38	Maximum	0.38	MM	0.44	MM	0.39
28	SM	0.13	MM	1.00	SM	0.16	MM	0.43
29	Maximum	1.00	Maximum	0.19	Maximum	1.00	Maximum	0.73
30	Maximum	1.00	Maximum	0.13	SM	0.16	Maximum	0.57
31	MM	0.06	Maximum	1.00	MM	0.13	MM	0.39
32	SM	0.09	Maximum	0.13	SM	0.41	Moderate	0.16
33	Maximum	1.00	Maximum	1.00	Maximum	1.00	Maximum	1.00

Source: Research data.
Legend: SM = slightly moderate, MM = moderately maximum, P = participant, W1 = weight 1, W2 = weight 2, W3 = weight 3, Pert = pertinence.

Table 2 – Difficulty and (dis)comfort pattern of the participants in linguistic terms and respective pertinence with the use of the bag with irrigation valve, according to the attributes bag cleaning, odor control and gas removal and at moment T_1. Niterói, Rio de Janeiro, Brazil, 2020

P	Bag cleaning (W3)	Pert	Odor control (W2)	Pert	Gas removal (W1)	Pert	Result	Weighted Pert
	Difficulty at moment T_1						Discomfort Pattern at moment T_1	
2	Minimum	1.00	MM	0.28	Moderate	1.00	SM	0.76
4	MM	0.22	SM	0.19	MM	0.19	MM	0.21
5	MM	0.25	SM	0.22	SM	0.22	MM	0.24
6	Maximum	1.00	Moderate	1.00	MM	0.25	Maximum	0.88
7	MM	0.24	MM	0.24	MM	0.27	MM	0.25
8	MM	0.25	Moderate	1.00	MM	0.32	MM	0.51
9	MM	0.24	MM	0.22	MM	0.31	MM	0.25
10	MM	0.25	Maximum	1.00	MM	0.24	MM	0.50
11	MM	0.27	Moderate	1.00	Moderate	1.00	MM	0.64
12	Maximum	1.00	Moderate	1.00	Maximum	1.00	Maximum	1.00
13	Moderate	1.00	MM	0.22	Moderate	1.00	Moderate	0.74
14	MM	0.25	Maximum	1.00	MM	0.25	MM	0.50
15	Moderate	1.00	MM	0.24	Moderate	1.00	Moderate	0.75
16	Moderate	1.00	Moderate	1.00	Moderate	1.00	Moderate	1.00
17	SM	0.25	Maximum	1.00	Moderate	1.00	Moderate	0.63
18	Moderate	1.00	Moderate	0.25	MM	0.27	Moderate	0.63
19	MM	0.22	MM	0.09	SM	0.10	MM	0.16
20	SM	0.25	MM	0.06	SM	0.38	Moderate	0.21
21	Moderate	1.00	MM	0.09	Moderate	1.00	Moderate	0.70
22	MM	0.09	MM	0.22	MM	0.38	MM	0.18
24	Maximum	1.00	Maximum	1.00	Moderate	1.00	Maximum	1.00
25	Moderate	1.00	MM	0.35	Moderate	1.00	Moderate	0.78
26	MM	0.09	MM	0.09	MM	0.09	MM	0.09
27	Moderate	1.00	MM	0.38	Moderate	1.00	Moderate	0.79
28	Moderate	1.00	Maximum	1.00	Moderate	1.00	MM	1.00
29	MM	0.28	MM	0.19	MM	0.44	MM	0.28
30	MM	0.09	MM	0.13	Moderate	1.00	MM	0.26
31	MM	0.13	Moderate	1.00	MM	0.06	MM	0.41
32	Moderate	1.00	MM	0.13	Moderate	1.00	Moderate	0.71
33	MM	0.16	Maximum	1.00	MM	0.16	MM	0.44

Source: Research data.
Legend: SM = slightly moderate, MM = moderately maximum, P = participant, W1 = weight 1, W2 = weight 2, W3 = weight 3, Pert = pertinence.

Table 3 – Linguistic terms and weighted pertinence between moments T_0 and T_1. Niterói, Rio de Janeiro, Brazil, 2020

	Moment T_0		Moment T_1	
Participant	Discomfort	Weighted pertinence	Discomfort	Weighted pertinence
2	Maximum	0.76	SM	0.76
4	Maximum	0.73	MM	0.21
5	Maximum	0.74	MM	0.24
6	Maximum	1.00	Maximum	0.88
7	MM	0.22	MM	0.25
8	Maximum	1.00	MM	0.51
9	Maximum	0.74	MM	0.25
10	MM	1.00	MM	0.50
11	MM	0.52	MM	0.64
12	Maximum	0.88	Maximum	1.00
13	MM	0.23	Moderate	0.74
14	Maximum	0.88	MM	0.50
15	Maximum	0.62	Moderate	0.75
16	MM	0.51	Moderate	1.00
17	Moderate	0.52	Moderate	0.63
18	MM	0.75	Moderate	0.63
19	MM	0.70	MM	0.16
20	Moderate	0.07	Moderate	0.21
21	MM	0.70	Moderate	0.70
22	MM	0.40	MM	0.18
24	Maximum	0.90	Maximum	1.00
25	MM	0.63	Moderate	0.78
26	MM	0.20	MM	0.09
27	MM	0.39	Moderate	0.79
28	MM	0.43	MM	1.00
29	Maximum	0.73	MM	0.28
30	Maximum	0.57	MM	0.26
31	MM	0.39	MM	0.41
32	Moderate	0.16	Moderate	0.71
33	Maximum	1.00	MM	0.44

Source: Research data.
Legend:SM = slightly moderate, MM = moderately maximum

■ DISCUSSION

It is important to highlight the originality of this study when verifying the positive effect of a technology that was proposed to minimize the discomfort of colostomized people.

The participants of this study presented characteristics similar to other previously published studies, with regard to gender, age and marital status[14,15] In this group, the participation of men with a medical diagnosis of rectal cancer prevailed, corroborating the greater risk of developing colorectal cancer throughout life. Among men, about one in 23 (4.4%) and in relation to women, one in 25 (4.1%)[15].

Another relevant factor that stands out in the characterization of the participants is about the marital status and the number of people who live with the colostomized patient. In addition, the number of participants married and living with one to two people predominated. This situation is directly related to body image, psychic functions and several factors that influence sexual activity and well-being. The family, partners and friends facilitate the process of rehabilitation, maintenance, coping and adaptation of the current or permanent life condition of the ostomized person[16].

It was considered that despite the different education levels presented by the participants, all were able to understand the entire process, that is, they knew how to deal with the proposed device, a fact considered fundamental for self-care, regular monitoring of health, nutrition, hygiene, among other conditions established after the surgery[17].

Regarding the evaluation of the attributes established in this study, the attribute "bag cleaning" stands out. Although the guidance in relation to the traditional bag are aimed only at removing the feces and cleaning the drainable area using toilet paper or wet wipe[18], many study participants declare that they do not use this practice, claiming they feel "dirty", having to wash the inside of the bag, as a basic need for physical comfort.

This condition highlights that the preference for using water to sanitize the traditional bag can cause the device to come off, although it cannot be considered an isolated factor. Several other elements can compromise the adherence of the bag to the skin, as it is only adhered by an adhesive plate. In this sense, an aspect considered important is the location of the stoma, because the further below the waistline it is fixed, the more it moves, causing detachment, since it may be over the leg joint. In addition, detachment may occur due to poorly applied adhesives, their incompatibility with the skin or carelessness due to having the bag too full, causing weight on the adhesive plate[19].

The traditional bag has a single opening at the bottom, which is used to eliminate feces and eject water for cleaning, causing a counterflow. Due to this misfit, it is believed that the use of the bag with the irrigation valve, as it has another access route in the upper part, exclusively for water entry, may reduce contact with feces, thus facilitating the process of cleaning without compromising the adherence of the bag.

Facilitating cleaning, reducing bag manipulation may avoid complications such as bag detachment and peristomal dermatitis, a fact that requires nurses to use creative strategies to promote care that involves the correct application and use of equipment and accessories to promote patient comfort[20].

Regarding the attribute "odor control", it is noteworthy that during the first evaluation, the participants considered any form of odor control impossible. However, in the second evaluation, they realized that when injecting the water through the irrigation valve, located in the upper part of the bag, there would be no need to direct the lower edge upwards, in order to throw the water inside the bag. Because, in addition to the discomfort of visualizing the fecal content and the direct inhalation of the odor, it would still be necessary to "shake" the bag to distribute the water throughout inside, to promote the removal of waste.

So, the attribute "odor control" presented a positive result during the use of the proposed product, considering that it provided greater agility in the cleaning process and reduced the spread of odors on the user's face and in the environment where occurs the manipulation of the bag.

Regarding the attribute "gas removal", through the colostomy, stands out the use of bags with or without activated carbon filter. The activated carbon filter aims to gradually release gases, while retaining unpleasant odors, preventing them from being noticed by other people. The retention of gases released through the stoma can distend the bag and compromise its adherence, depending on the volume.

However, in the absence of the filter attached to the bag, the gas removal is done through the opening of the hole at its bottom, even if there is no feces or there is a small amount[18], making the procedure harder and requiring a suitable environment. With the use of the bag with irrigation valve and the syringe for aspiration of gases, it is possible to perform a safe and immediate emptying, reducing the volume of the bag and, consequently, the discomfort.

From the elements presented in this study, new interventions for care may emerge, in addition to enabling the improvement and emergence of other innovations, with the intention of increasingly helping colostomized people in the process of adaptation, maintenance and recovery of physical

health, psychic and social. It is the application of science in practice, with the production of beneficial results for society, from the testing of its feasibility and acceptance[21].

Regarding the limitations of the study, the lower number of participants compared to that indicated in the sample calculation is considered, mainly justified by the fact that the data collection was conducted during the initial pandemic period of covid 19, hindering the acceptance of the home visit by the participants. In addition, there is a lack of funding to cover the costs of bags and valves during the research.

■ CONCLUSION

The use of fuzzy logic allowed the participants to express themselves on the attributes considered relevant, making it possible to verify the effect of the bag with irrigation valve on the discomfort pattern of the colostomized person.

After comparing the patterns of (dis)comfort presented by the study participants at moments T_0 and T_1, that is, before and after the use of the bag with irrigation valve, it was possible to verify a positive migration in linguistic terms and/ or an increase in pertinence in the same category, which demonstrated the positive effect of the bag with irrigation valve on the discomfort pattern of the colostomized person.

Despite the positive results and the feasibility of reducing the discomfort of colostomized people with the proposed technology, there is a need for new studies, with an increased number of participants, in addition to randomized clinical trials, for the purpose of contribute to the practice based on evidence about the results analyzed here.

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The authors declare that there is no conflict of interest.

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