Innovative technology for colostomy irrigation: assessing the impact on patients

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Aim. The main purpose of the trial was to evaluate the opinions expressed by a sample of subjects with permanent colostomy, as a result of the use of a new device designed for the execution of transtomatal intestinal irrigation; their feedback was analyzed in relation to the concept of Quality of Life.

Methods. The device was tested on a sample of 14 colostomized patients (10 men and 4 women, aged between 42 and 77 years) who were used to perform intestinal irrigation procedures independently and routinely, with standard technique. After testing the new device, the patients included in the study were asked to fill out a questionnaire built ad hoc for their situation.

Results. The analysis of the data collected led to the following conclusions: 93% of the patients described the new irrigation method as simpler than the standard procedure; the majority of the patients assessed bowel emptying as good; 64% of patients reported excellent comfort experienced during the procedure; the presence of a regulator to adjust the instillation speed of water into the intestinal lumen was considered useful to control the flow of the incoming fluid.

Conclusion. The use of the device guaranteed: psychological tranquility, minimum manual intervention, full achievement of the expected results and decrease in the issues normally encountered with the standard irrigation method. The practical features of the new device ensure easy and straightforward carrying out of the procedure; this ease of use affects the stomized patient's everyday life by reducing the time of procedure completion, thus positively influencing the perception of the patients' Quality of Life.

Key words: Colostomy - Therapeutic irrigation - Surgical stomas - Colostomy Irrigation - Nursing care.

The term "enterostomy", by definition, is a surgically created opening in the abdominal wall, to which a piece of intestine is attached in order to allow the release of organic material. The stoma has no nerve endings or muscles, so the problem that the stomized patient must face on a daily basis is the inevitable loss of continence. This issue has an undoubtedly profound impact at a level of physical, emotional and social development of the patient; it can cause a sense of frustration and embarrassment. Curbing this type of problem is an important step for patients with permanent stoma, since it allows improving everyday life quality and ensuring greater psychological tranquility.

Currently, there are several methods to control feces production and evacuation: proper diet, drug control of the discharges.

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and transtomal intestinal irrigation. Several scientific publications and experience in clinical practice showed that the first two schemes are not individually sufficient to ensure good control of continence; on the contrary, irrigation is considered reliable and can bring a number of advantages. It is referred to as a rehabilitation technique based on the principle of "colon cleansing": the introduction of drinking water at body temperature into the intestine, through the stoma, in order to eliminate mucus, feces, gas and use a small collection device; it enables the patient to acquire mechanical continence: an interval free from fecal discharges ranging from 24 to 72 hours. When used regularly, this method can reduce the risk of alterations in peristomal skin, health management costs (there is a reduced consumption of collection pouches), sexual issues, and anxiety, and it can guarantee safety, greater social participation and the ability to follow a diet. It is only recommended to compliant patients, with good oculo-manual coordination, holders of a permanent left colostomy, transversostomy or stoma of the ascending colon. It is contraindicated in the presence of inflammatory bowel diseases, stomal complications, chemotherapy or radiotherapy.

The traditional technique for intestinal transtomal irrigation involves the use of a bag containing water, a drip chamber tube and an anatomical cone to be positioned inside the stoma (standard irrigation set); the physical principle that affects water flow that descends from the fluid bag of the device is gravity.

The test carried out on a sample of patients involved the use of a device as an alternative to the above-mentioned standard irrigation set for the implementation of the entire procedure. The ultimate goal was to identify the outcomes highlighted by the patients, in order to understand how the new technique could affect the quality level of their everyday life; in particular, with reference to the relationship between validity of methodology, improved stoma management, and personal vision of wellness.

Materials and methods

The research was conducted in the period between May and September 2014, within the Ostomized Surgery of the Istituto Ospedaliero Fondazione Poliambulanza on a sample of 14 patients (10 men and 4 women) aged between 42 and 77 years. The study was approved by the committee on research ethics at the institution in which the research was conducted and any informed consent from human subjects was obtained as required.

The criteria for inclusion in these tests were the following: subjects with permanent colostomy, self-sufficient, able to express a valid opinion, autonomous in the management of the standard irrigation technique, in contact with the mentioned surgery, and ordinarily performing bowel irrigation (rate 71% of the sample patients practice the procedure every 48 hrs, while 29% every 24 hrs). The number of people involved was evidently limited, since not all patients still in contact with the hospital independently and routinely used the irrigation technique. The device (IryPump®, B. Braun) with which the test was carried out is basically composed by a portable electric pump designed to provide an alternative to the standard irrigation technique, with valve to adjust the flow velocity and modulate the release of water through 6 speed levels (from one to six) and a water container that can hold a volume of 1500 ml.

The set is completed by an irrigation tube and anatomical cone, similar to that found in the standard irrigation set.

The new procedure main goal is to maintain a regular control of bowel movement. Similarly to the standard method, this all happens after instillation of a given volume of warm water in the stoma. The main difference between the two techniques is that in the new one, water instillation is regulated by an electric pump and a valve setting the flow rate; these features allow colon cleansing to be performed with constantly controlled pressure, which outdoes the cleansing with standard method, which is done by spilling. The constantly controlled pressure is, in fact, effective and beneficial because it prevents the slipping of feces on the intestinal mucosa.
and guarantees, therefore, a much more accurate fecal discharge.\textsuperscript{11}

Before starting the test, it was deemed necessary to quantify the value of the constant pressure of water instilled in the intestine. Starting from the theorem of Bernulli and the law of Leonardo, it was determined a rough estimate of the pressure value for each speed level set on the device: with the Speed set to level 1 the pressure was 391 Pa (\(v=1\); \(P=391\) Pa), (\(v=2\); \(P=592\) Pa), (\(v=3\); \(P=827\) Pa), (\(v=4\); \(P=906\) Pa), (\(v=5\); \(P=1000\) Pa), (\(v=6\); \(P=1100\) Pa).

**Test**

The test was conducted according to a precise pattern:
1. The device was shown to the patients.
2. The general operation of the device was described to the patients.
3. They were explained the nature of the test.
4. The practical test was then performed in the surgery, under the supervision of a stomatherapist nurse.
5. The patients were given a questionnaire built \textit{ad hoc} for the test.

The questionnaire mentioned is the primary tool which the research is conducted with; it consists of nine questions in total and it is divided into 2 different parts. The first consists of four questions, which investigate the gender-related data as at the date of stoma, and particularities related to the standard practice already used by patients. The second one contains both closed and open questions involving open and free answers.

All the questions included in the second part of the questionnaire were selected to identify the perceptions of patients, evaluating the effectiveness of the new procedure and the impact that this may have in terms of concrete and daily management of the stoma.

The complete compilation has been handled autonomously by the patients, in respect of their own time and in a place guaranteeing tranquility and privacy.

Anonymous questionnaires were stored in a special box and analyzed globally at the end of all 14 tests.

**Results**

The data collected and the results of the following parameters were analyzed: colostomy management experience, ease of implementation of the new procedure, ability to manage the incoming water flow, comfort during the procedure execution, achievement of expected results, overall evaluation of the new irrigation system.

![Figure 1.—Representation of the sample examined.](image-url)
**Experience in managing a colostomy**

In Figure 1 we can see a graphic representation of the answers given to the third question of the questionnaire; the sample was divided into three different groups: people in the first group got a colostomy before year 2000, the second group includes patients who had surgery between the 2000 and 2010, and the third includes all subjects living with a stoma since at least 2011.

**Ease of implementation of the new procedure**

The second chart (Figure 2) shows the percentage of subjects who, following a first and only test of the device, considered the
new transtomial irrigation procedure easier to perform than the standard one. Of the 14 patients included in the study, 13 answered positively and one negatively; they were then asked to motivate the answer by adding a clear explanation.

**Ability to manage the incoming water flow**

The graph in Figure 3 clearly shows how the sample of subjects was divided into two main groups: 50% answered "good" and 43% answered "excellent"; none of the participants answered "sufficient".

**Comfort experienced during the execution of the procedure**

None of the subjects in Figure 4 judged the comfort inadequate. Even in this case, the sample split into two positive answers.

**Achievement of expected outcomes**

The analysis of Figure 5 shows that most of the subjects to whom the questionnaire was submitted believed that intestinal flushing was effective. 50% answered "good" and 43% "excellent".

**General assessment of the new irrigation system**

Observing the last graph in Figure 6 it can be seen that there is a clear predominance of "Yes" answers. 86% answered "yes" and only 14% answered "no". At the end of the question they were asked to write some additional notes about the effect that the use of the device would bring in terms of day-to-day management of the stoma.

**Discussion**

The sample examined, as we pointed out earlier, is restricted, but mainly formed by individuals who had had permanent colostomy for at least 4 years (3 people had undergone the operation before 2000 and 6 people between 2000 and 2010). Patients, who have been living for a long time with a colostomy, have a deeper knowledge about themselves, their bodies and their feelings; we can therefore deduce that patients included in the research not only have a good degree of experience, but also great ability in assessing the impact of a new device. The opinions reported in the compilation of
the questionnaire are, therefore, obviously supported by competence and validity. Statistically speaking, this can be defined "a relevant datum".

It was deemed appropriate to proceed to a direct comparison between the standard and the innovative technique, comparing the two methods on a precise feature: ease of use. Ninety-three per cent of the sample stated that the new machinery can simplify the procedure, compared with 7% who gave a negative response; however, to better understand this response, the subjects were asked to explain the reasons. The main reasons were as follows: the new technique is easier because it is faster (5 out of 14 persons); more adaptable to various needs (the presence of the electric pump avoids the need to hang the sprinkler bag, which is used in the standard procedure).
(2 out of 14 users); the water entry into the lumen is more constant (3 out of 14); and there are no sliding issues (2 out of 14). A subject did not respond and another (representing the remaining 7%) gave a negative reply, explaining that he considered the new technique as simple as the standard one. The ease of use that we underlined carries with it the idea of practicality; this close correlation between the two concepts implies that if a procedure is simple, than a short time is required to implement it. This aspect needs strong consideration, given that the daily hours reserved to irrigation are one of the causes that drive some patients to stop or not start it. The innovative technique is faster and, therefore, in a way beneficial to an everyday management of the issue.

The emphasis is placed on the analysis of the water entrance flow regulator features; a purely technical feature, which cannot prevent from identifying advantages and/or disadvantages of the new practice. Thinking about this mechanical component means considering the ability to control more precisely the instillation speed; this aspect greatly affects the outcome of irrigation. The sample of subjects generally expressed a positive opinion about the accessory; this indicates recognition of its usefulness in relation to the success of the procedure and a consequent facilitation of colostomy control.

It is incorrect to argue about a new clinical practice without having evaluated the aspect of patient comfort. With the word “comfort” we are not referring to mere collection of elements ensuring comfort, but to a more abstract view of its meaning, denoting the tranquility and wellbeing detected by the patient during the procedure. The results shown in the graph show that the use of this innovative method is greatly appreciated by the patients and ensures a high level of perceived benefit: 64% of the sample called it “excellent” and 29% “good”. It would be rather pointless to propose a new type of procedure if the latter creates discomfort to the stomized person; it is essential to maintain a balanced ratio between the benefit perceived during the technique and the positive outcomes that it can offer in terms of stoma management.

The success of irrigation generally depends on the emptying of feces contained in the intestine, which must be thorough and effective. The standard technique enables optimal fecal emptying. It was then asked to the patients included in the study how they judged the removal of organic material by the device tested; it appears evident that the majority has considered the evacuation good. This aspect is of primary importance within the experimentation, considering that, at the basis of any other consideration, there must be a concrete achievement of the purpose; this is the aspect that most affects the possibility that the new clinical practice can improve the control of the stoma activity.

The final question of the questionnaire was meant to investigate the real ability of the innovative method to influence the life of the stomized patient. The question was placed in closed form, with an opportunity to indicate additional opinions ("additional notes"), in order to clarify the reasons that caused the subject to give a certain response. Most of the candidates (86%) said that the device can be considered advantageous in facilitating the management of colostomy. The reasons given by the patients are the following:

- The pressure of water in the intestinal lumen is constant.
- The device is more convenient than the standard set because the irrigation bag must not be hung.
- The water flow in the intestinal lumen never stops.
- Feces are expelled much faster.
- Water enters with more strength.
- The technique helps to be psychologically more tranquil.
- It causes less discomfort than the standard method: the pain that usually accompanies the final phase of the expulsion of feces is not perceived.
- Irrigation takes less time.
- It is easier to handle the water speed through the device controller.
Manual intervention of the patient is reduced to a minimum: the device plays the irrigation technique almost autonomously.

Considering both the percentage of answers and their explanation, it must be acknowledged that the new clinical practice has been considered positively in relation to the improvement of the stoma management. Despite this, however, certain aspects of the procedure were criticized: 5 persons out of 14 stated that the device seemed too bulky to be taken on trips; a person has expressed concern about the rigidity of the irrigator tube and finally a patient has found it difficult to distinguish the numbers placed on the speed level control ring.

Conclusions

In stomatherapy the continuous improvement of treatment, clinical practice and care techniques are essential in order to provide a solid help for the patient. It is essential that the stoma patients have the ability to learn and try new procedures in order to address their lives as autonomously as they can.

The testing of an innovative method for irrigation is assessed, therefore, in relation to the changes that it can produce in the structuring of everyday life both in the control and management of the stoma, directly influencing the psycho-social expectations.

According to the findings of the data analysis, different considerations arise. The main opinion, underlined in the debate, is that the device tested ensures a clear benefit to the patient not only for the comfort felt during the execution, but also for the results it produced. Secondly, it is important to emphasize the comparison between the new and the standard method: the first one is undoubtedly easier to run. This peculiarity stems from the practical nature and the simplicity of the device itself. The most important aspect of its comfort is that it greatly affects the stoma patient’s everyday life, clearly reducing the completion time of the entire procedure. The strong correlation between the concept of usability and a faster method showed the influence that the device can be used not only at a domestic level, but also at a hospital level; the availability of the device inside a stoma surgery or a department would allow a reduction in the duration of the procedure and improve the management of the department itself.

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