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Pilot study on the applicability and functionality of an ileostomy catheter: experience report**

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ABSTRACT

Objective: To report a pilot study analyzing the applicability and functionality of an ileostomy catheter. **Method:** This is an experience report on the applicability and functionality of the catheter during insertion, in directing the effluent to a temporary collecting device, and in stabilization. Data were collected through systematic observation and video recording of one adult participant. **Results:** The innovative product, named the TomJeff® catheter, was inserted without difficulty; the effluent was directed to the temporary collecting device; and the catheter remained stable. The participant reported discomfort, pain, cramping, and fear from the period prior to insertion through removal; however, all symptoms were tolerated. Video recording allowed documentation of behaviors, expressions, and interactions, providing rich data and enabling review of all stages; however, it reduced spontaneity. **Conclusion:** The study enabled the identification of necessary adjustments to the catheter and validated its feasibility. Although it does not allow for generalizations, the results provide valuable support for the next steps of the research. The modifications made to the device, including resizing the catheter to facilitate insertion, demonstrate how technological development aligned with clinical practice can contribute to improving the user experience.

DESCRIPTORS: Nursing care. Surgical stomas. Ileostomy. Health technology assessment. Enterostomal therapy.

Estudo piloto da aplicabilidade e funcionalidade de cateter para ileostomia: relato de experiencia

RESUMO

Objetivo: Relatar estudo piloto para análise de aplicabilidade e funcionalidade de um cateter para ileostomia. **Método:** Trata-se de um relato de experiência da aplicabilidade e funcionalidade do cateter no processo de inserção, na condução do efluente para o equipamento coletor provisório e na estabilização. Os dados foram coletados por observação sistemática e filmagem em uma participante adulta. **Resultados:** O produto inovador, denominado Cateter de TomJeff®, foi inserido sem dificuldade; o efluente foi conduzido para o dispositivo coletor provisório; e o cateter permaneceu estável. A participante relatou desconforto, dor, cólica e medo desde o período prévio à inserção até a sua remoção; entretanto, houve tolerância a todas as condições. A filmagem permitiu registrar comportamentos, expressões e interações, oferecendo riqueza de dados e possibilidade de revisão de todas as etapas; porém, inibiu a espontaneidade. **Conclusão:** O estudo permitiu

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identificar ajustes necessários ao cateter e validar sua viabilidade. Embora não possibilite generalizações, os resultados oferecem subsídios valiosos para os próximos passos da pesquisa. As modificações realizadas no equipamento, dentre elas o redimensionamento do cateter para facilitar a inserção, evidenciam como o desenvolvimento tecnológico alinhado à prática clínica pode contribuir para a melhoria da experiência do usuário.

DESCRITORES: Cuidados de enfermagem. Estomas cirúrgicos. Ileostomia. Avaliação das tecnologias em saúde. Estomaterapia.

Estudio piloto sobre la aplicabilidad y funcionalidad de un catéter para ileostomía: relato de experiencia

RESUMEN

Objetivo: Informar un estudio piloto para analizar la aplicabilidad y funcionalidad de un catéter para ileostomía. **Método:** Se trata de un relato de experiencia sobre la aplicabilidad y funcionalidad del catéter en el proceso de inserción, en la conducción del efluente hacia el dispositivo colector provisional y en la estabilización. Los datos fueron recolectados mediante observación sistemática y filmación en una participante adulta. **Resultados:** El producto innovador, denominado Catéter de TomJeff®, se insertó sin dificultad; el efluente fue conducido hacia el dispositivo colector provisional; y el catéter permaneció estable. La participante refirió malestar, dolor, cólico y miedo desde el período previo a la inserción hasta su retirada; sin embargo, toleró todas las condiciones. La filmación permitió registrar comportamientos, expresiones e interacciones, ofreciendo riqueza de datos y la posibilidad de revisar todas las etapas; sin embargo, inhibió la espontaneidad. **Conclusión:** El estudio permitió identificar ajustes necesarios en el catéter y validar su viabilidad. Aunque no permite generalizaciones, los resultados ofrecen insumos valiosos para los próximos pasos de la investigación. Las modificaciones realizadas en el dispositivo, entre ellas el redimensionamiento del catéter para facilitar la inserción, evidencian cómo el desarrollo tecnológico alineado con la práctica clínica puede contribuir a mejorar la experiencia del usuario.

DESCRIPTORES: Cuidados de enfermería. Estomas quirúrgicos. Ileostomía. Evaluación de tecnologías en salud. Estomaterapia.

INTRODUCTION

People with intestinal elimination stomas experience difficulties related to adaptation and complications resulting from the procedure, particularly those associated with skin damage[1,2].

When a nurse or another trained professional performs preoperative stoma site marking for the surgical creation of the stoma, there is a reduction in postoperative complications[3] and in the costs related to care[4]. Inadequate marking or the absence of marking may lead to problems such as stoma retraction, poor location, difficulties during the surgical procedure, and poor fitting of the collecting device. These problems contribute to the development of severe dermatitis, effluent leakage, unpleasant odors, and social insecurity[5].

Despite advances in products and adjunctive materials, current solutions focus on the interface between the skin and the device without addressing the main cause of complications: the continuous contact of intestinal effluent with the skin, especially in ileostomies. In addition, randomized and multicenter studies are needed to evaluate the effectiveness of alternatives to devices and adjunctive materials, revealing an important gap in the scientific literature[6].

A study involving 144 people with intestinal elimination stomas reported that 65 (45%) experienced skin complications within 24 months after surgery, and 49 (34%) within the first six months, which were resolved only among those who underwent reversal[7]. In addition to this issue, the products available to prevent complications have been shown to be ineffective in approximately 35% of cases[8].

To offer an alternative that minimizes complications, a catheter for ileostomy was developed with the function of directing the effluent to a temporary collecting device. The innovative catheter is a tube made of biocompatible silicone with inlet and outlet openings, measuring 9 cm in length and 2.5 cm in diameter in a cylindrical shape, allowing the flow of effluent from the intestine to the temporary collecting device with minimal risk of leakage. The product had an invention patent registered and granted by the National Institute of Industrial Property (INPI) under BR 102016024362-9.

OBJECTIVES

The present article aimed to report a pilot study to analyze the applicability and functionality of a catheter for ileostomy.

METHODS

This is an experience report limited to a pilot study regarding the applicability and functionality of the TomJeff® Catheter. An experience report is a methodological approach that describes and analyzes the author's concrete experiences in a given context, highlighting lessons learned, challenges, and critical reflections on professional practice, thereby contributing to the advancement of knowledge in the field[9].

The pilot test was conducted in partnership with the Municipal Government of Ponta Grossa, in the state of Paraná, with one participant selected from among the patients of the Municipal Center for Ostomies and Special Programs (CEMOPE in Portuguese). CEMOPE provides reception, guidance, and care for people with ostomies and has a multidisciplinary team composed of one enterostomal therapist and two nursing technicians.

Data collection involved one female participant over 18 years of age with a loop ileostomy for more than 30 days, presenting high output and liquid effluent. The participant was not using medication intended to form fecal bulk, maintained her usual diet, and continued her work activities normally. For convenience, data collection was conducted at the participant's home.

The analysis of the catheter's applicability and functionality was conducted through systematic observation and video recording using a Galaxy J7 Prime® (Samsung®) mobile phone with a 1.6 GHz processor, a 13.0 MP camera, Full HD quality, and 32 GB of memory, attached to a tripod with additional lighting. Recordings were made using the Cinema FV–5 Lite application and were preceded by a pretest to adjust lighting, sound, camera positioning, and recording time.

The procedure was performed by a enterostomal therapist with nine years of experience, the principal investigator of the study, and lasted approximately 30 minutes.

After positioning the participant safely and comfortably, the sequence of the application was:

a. insertion of the catheter, leaving the internal portion within the ileostomy and the external portion on the skin;
b. fixation with a hydrocolloid adhesive base and fixation ring; and
c. attachment of a disposable collecting bag to the distal end.

During the test, the following operational and clinical variables were observed: ease of insertion (level of resistance, need for adjustments, and total insertion time); stability (maintenance of catheter positioning and absence of displacement during use); effluent conduction; pain (subjective perception of pain at the time of insertion and during use, assessed using the numerical pain scale[10]); leakage (occurrence and frequency of effluent overflow); and skin integrity (presence of irritation, redness, or lesions in the area in contact with the catheter).

Audio and video capture was continuous and uninterrupted, with the inclusion of a visible digital time marker in the recording. The images were labeled without personal identification, cataloged by date and time, and transferred to a cloud platform (Send Anywhere®).

For the qualitative analysis of the recordings, ATLAS.ti® 24 software was used, which enables the integration of textual, graphic, and audiovisual data. The recordings were segmented into thematic units corresponding to the stages of the procedure and the observed variables. Each segment was coded and categorized according to previously defined criteria, allowing the identification of performance patterns, technical difficulties, participant responses, and possible adjustments needed to the device.

The research was conducted in accordance with the ethical principles of Resolution No. 466/2012 and was approved by the Research Ethics Committee and the National Research Ethics Commission under Certificate of Presentation for Ethical Consideration (CAAE) 65537522.0.0000.0098. Participation was conditional upon signing the Informed Consent Form, and all recorded images were edited to preserve the participant's anonymity.

The pilot study aimed to evaluate the clinical applicability and functionality of the TomJeff® Catheter, verifying its technical and ergonomic feasibility before implementation in an expanded clinical trial. This stage made it possible to identify aspects related to ease of insertion, stability, comfort, safety, and peristomal skin integrity, supporting improvements in the design and technique for using the device.

RESULTS

During the pilot test, the clinical and functional performance of the TomJeff® Catheter was observed according to the previously defined variables (ease of insertion, effluent conduction, leakage, stability, peristomal skin integrity, and pain). Table 1 presents a summary of the observed data.

Table 1. Evaluation of clinical and operational variables during the pilot test of the TomJeff® catheter.

Observed variable	Description of findings
Ease of insertion	Insertion was performed without significant resistance; no repositioning was required. Total insertion time: 45 seconds (Figures 1 and 2).
Effluent conduction	The effluent began to be conducted through the catheter immediately after its introduction (Figure 3). Fluid intake was requested to stimulate effluent output, resulting in a rapid response with just under 400 mL of drainage.
Leakage	No effluent leakage occurred during the test (Figure 4).
Stability	The device remained fixed throughout the entire period of use (30 minutes), with no displacement (Figure 4).
Peristomal skin integrity	No irritation, redness, or lesions were observed in the contact area after use (Figure 4).
Pain	Score of 2 on the numeric pain scale (0–10), indicating mild discomfort only during insertion.

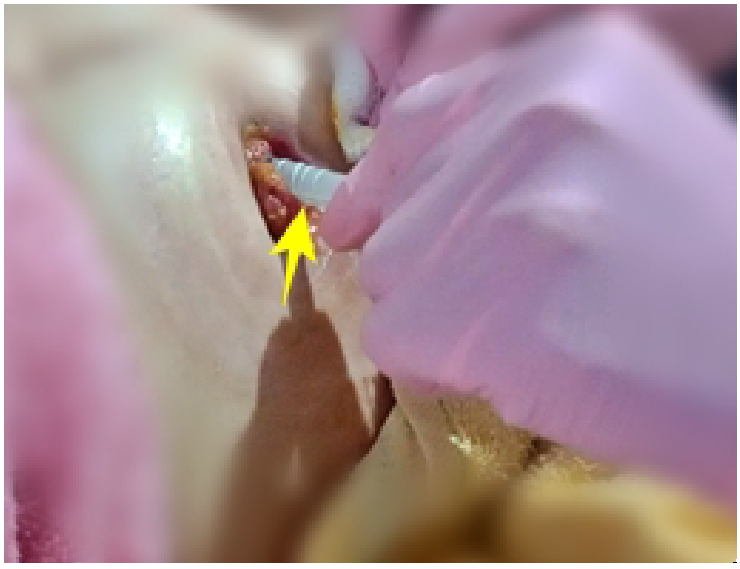

Figure 1. Catheter insertion. Ponta Grossa (PR), 2024.

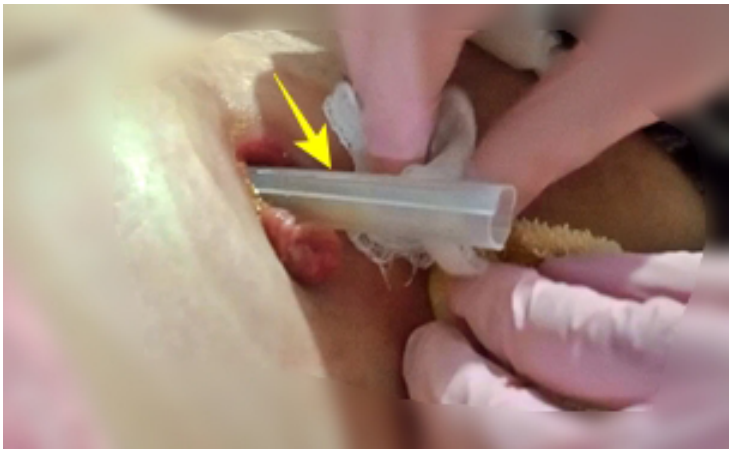

Figure 2. Catheter positioned. Ponta Grossa (PR), 2024.

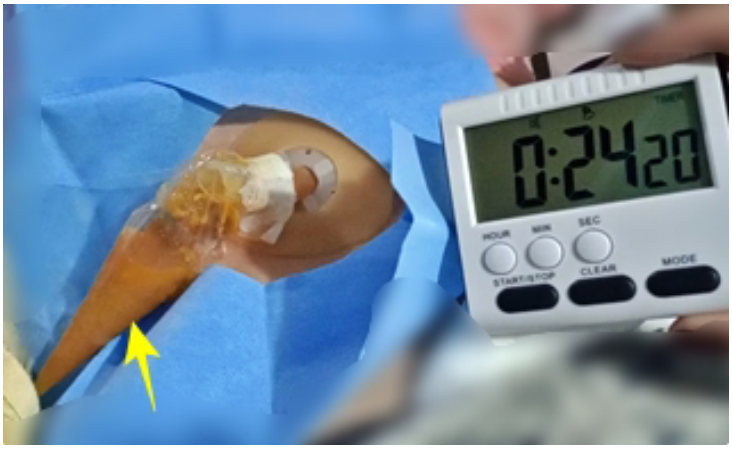

Figure 3. Large amount of effluent drained through the catheter. Ponta Grossa (PR), 2024.

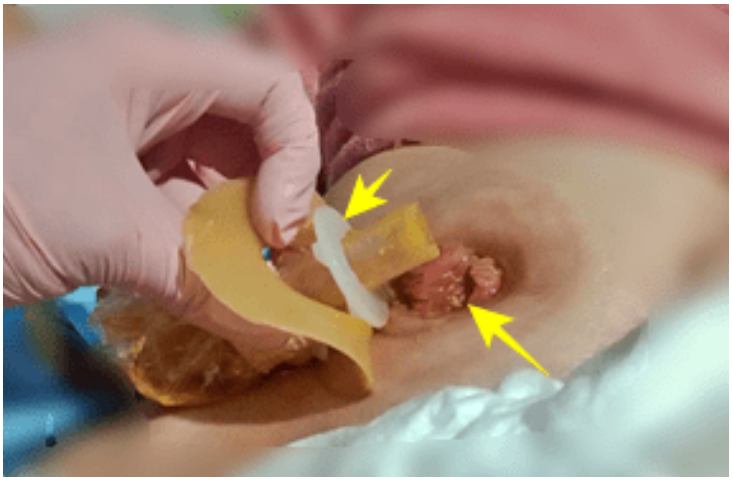

Figure 4. There was no leakage, and the ileostomy showed no change in color or moisture. Ponta Grossa (PR), 2024.

The pilot test revealed some difficulties in the adaptation, insertion, and stabilization of the catheter, indicating opportunities for improvement; however, it also demonstrated easy insertion, effective effluent conduction, absence of leakage, and stability with the hydrocolloid barrier. The participant reported discomfort, mild pain (score 2 on the numerical scale), cramping, and fear, but was able to tolerate the situation, with no persistence of symptoms at the end of data collection.

The qualitative analysis of the recordings confirmed good anatomical adaptation, continuous effluent flow, and adequate device adhesion. Overall, the TomJeff® Catheter showed satisfactory clinical applicability, comfort for the participant, and

preservation of peristomal skin integrity, reinforcing its technical and ergonomic feasibility and providing support for future expanded clinical trials.

DISCUSSION

The development and evaluation of innovative technology involve challenges that encompass technical, ethical, and social aspects.

Regarding the strategy and the data collection instrument, video recording provided the researcher with the advantage of revisiting the observed context as many times as necessary, enhancing the detailed analysis of each part of the procedure. However, filming also imposed limitations related to the influence of the camera on the participant's behavior, in addition to the need for rigorous care regarding the anonymity, storage, and confidentiality of the images. The presence of a systematic observation guide supported the data collection by providing a standard.

Even though this was a report of a pilot test, there was a scarcity of studies on ileostomy devices with characteristics similar to the catheter, which made it difficult to compare results. Given this gap, studies on colostomy irrigation were used as references, especially regarding cone insertion, to support the analysis of the catheter developed.

Catheter insertion revealed significant challenges; the visibility of the proximal opening facilitated the introduction of the device, but its advancement was hindered by the diameter of the intestinal loop lumen. Previous studies indicate that catheters adapted to the diameter of the stoma may facilitate this process, and the experience observed during the tests reinforced this need[11].

Although, in most cases, the process of colostomy irrigation is simple, challenges such as difficulties in the initial insertion of the cone may arise, especially in individuals with irregular or retracted stomas. In this context, the use of specific cones or technical adaptations may be necessary to ensure the safety of the procedure[11,12], an aspect analyzed in the present pilot study.

Catheter stabilization was a notable aspect; fixation with hydrocolloid plates was tested and showed good results. This approach not only ensured catheter stabilization but also allowed greater mobility for the participant and, although discomfort was present, minimized it, since effective sealing prevented leakage and irritation of the parastomal and peristomal skin.

Studies on colostomy irrigation emphasize the importance of equipment stabilization. Keeping the cone firmly positioned is crucial to ensure the effectiveness of irrigation, providing greater control over bowel evacuation. Proper stabilization offers important benefits, such as efficiency of the procedure, comfort, and predictability, in addition to reducing reports of discomfort, cone expulsion, the risk of leakage, and procedural ineffectiveness[11-16].

During the test, it was identified that fecal consistency, influenced by factors such as hydration, directly affected the effectiveness of the procedure. The liquid characteristic of the effluent allowed rapid and effective conduction. Therefore, it is hypothesized that this is a variable to be considered for the effectiveness of the catheter.

The adoption of strategies such as adjustments in the volume of water intake, dietary control, the use of appropriate equipment, and suitable techniques may improve effluent conduction during irrigation and provide greater comfort for the individual[16-19].

Catheter removal proved to be practical and safe, without causing trauma to the stoma and/or the parastomal and peristomal region. The choice of the type and size of the device was essential to ensure a more comfortable experience for the participant.

Cone removal is a crucial step in the irrigation process. After the water drains into the intestine, the cone should be carefully removed to avoid trauma to the stoma region and possible discomfort. The integrity of the stoma should be checked before and after the irrigation procedure. Repetitive trauma during insertion and removal of the cone may result in complications such as ulcerations or stenosis. In addition, improper use of the cone may cause irritation of the peristomal skin due to effluent leakage[14].

Another relevant aspect was the response to catheter insertion, with the participant reporting fear, cramping, and pain during the test. This perception may compromise adherence to the procedure, highlighting the importance of

adjustments in both the technique and the design of the equipment. The use of biocompatible materials and the application of strategies such as explaining the catheter insertion and irrigation procedures were fundamental to improving acceptance of the procedure.

Fear and cramping are common experiences among individuals who perform colostomy irrigation. Although these signs and symptoms may be challenging, the implementation of appropriate techniques and the provision of support may improve adherence to the procedure. As individuals gain confidence in using the irrigation equipment and master the technique, the perception of these symptoms tends to decrease, being described as minimal or non-existent in most cases[20].

The reported experience suggests that the combination of appropriate design, efficient stabilization, and compatible materials was decisive for the success of the procedure, promoting the applicability and functionality of the catheter and ensuring procedural safety.

Study Limitations

This was a pilot study with a single participant, which prevents the generalization of the findings. In addition, the participant had a high-output ileostomy, a condition that may have influenced the results. The investigator's interference in encouraging increased fluid intake is also acknowledged, which may have directly affected the analyzed variables. However, these conditions and interventions were necessary to identify the real indication for the use of the catheter, contributing to the refinement of the technology and to the design of future studies.

Recommendations

The development of the TomJeff® Catheter requires essential adjustments, such as making insertion more practical through the development of an applicator and improving fixation by using the adhesive base of collecting devices. These adjustments aim to meet the needs of people with an ileostomy, providing a product that truly contributes to improving quality of life.

CONCLUSION

The pilot study demonstrated that the TomJeff® Catheter showed easy insertion, adequate stability, absence of leakage, and good tolerance by the participant, without compromising skin integrity, demonstrating its technical and ergonomic feasibility for use in people with an ileostomy. The test allowed the identification of necessary adjustments to the device, such as resizing to facilitate insertion, showing that technological development aligned with clinical practice contributes to improving the user experience. Although the findings do not allow generalization, they provide valuable support for the next steps of the research and for future expanded clinical trials.

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Research data availability: All data were generated or analyzed in the present study.
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