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ARTÍCULO ORIGINAL

Comparative simulation study of bladder catheterization using the Foley-type catheter and the T-Control® catheter

Estudio comparativo de simulación del sondaje vesical utilizando el catéter tipo Foley y el catéter T-Control®

Manuel Luque González*[1], Clara Armas Moreno[1], Max Mòdol Vidal[1], Pedro Raul Castellano Santana[2], Marta Serrano Muñoz[1], Giulio Fenzi[3], Mariana Ferrandini Price[3], Manuel Pardo Ríos[3]

1. Rethink Medical SL, Las Palmas de Gran Canaria, Las Palmas, España
2. Universidad de Las Palmas de Gran Canaria (ULPGC), Las Palmas de Gran Canaria, Las Palmas, España
3. Universidad Católica San Antonio de Murcia (UCAM), Guadalupe, Murcia, España

Abstract

In evaluating medical devices, usability and satisfaction are critical. T-Control® is a novel silicone catheter with an integrated fluid control system. This study analyzed usability, satisfaction, and workload perceived by 58 final-year nursing students during bladder catheterization simulations. Participants were randomly assigned to use either a conventional Foley catheter or T-Control®. Workload was assessed using the NASA-TLX questionnaire, while satisfaction was measured with an ad-hoc questionnaire. Video analyzed by experts recorded spillages and contamination incidents. Foley catheters showed higher physical (p=0.047), temporal (p=0.004), and frustration demands (p=0.031), with more spillages during insertion (79.17% vs. 4.17%; p<0.001) and urine collection (54.17% vs. 16.67%; p=0.007). T-Control® scored higher in satisfaction (7.44 vs. 5.12; p<0.001), with 100% of users affirming its ideal standards, compared to 54% for Foley. T-Control® demonstrates the potential to reduce risks in catheterization, highlighting the importance of user-driven innovation in improving medical devices.

Keywords: Medical devices. Nursing. Nursing students. Simulation. Urinary catheterization.

Resumen

En la evaluación de dispositivos médicos, la usabilidad y satisfacción son clave. T-Control® es una sonda de silicona con control de fluidos integrado. Este estudio analizó la usabilidad, satisfacción y carga de trabajo percibida por 58 estudiantes de enfermería de último año durante simulaciones de sondaje vesical. Los participantes usaron aleatoriamente una sonda Foley convencional o T-Control®. La carga de trabajo se midió con el cuestionario NASA-TLX y la satisfacción con un cuestionario *ad hoc*. Los expertos analizaron las simulaciones para registrar derrames y contaminaciones. Foley mostró mayores demandas físicas (p=0,047), temporales (p=0,004) y de frustración (p=0,031), con más derrames durante la inserción (79,17% vs. 4,17%; p<0,001) y recolección de muestras de orina (54,17% vs. 16,67%; p=0,007). T-Control® obtuvo mayor satisfacción (7,44 vs. 5,12; p<0,001) y un 100% de aprobación frente al 54% de Foley. T-Control® reduce riesgos y resalta la importancia de innovar en dispositivos médicos.

Palabras clave: Dispositivos médicos. Enfermería. Estudiantes de enfermería. Simulación. Sondaje vesical.

***Correspondencia**
Manuel Luque González
mluque@rethinkmedical.es

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Introduction

Clinical simulation for designing medical devices is fundamental for the development of competencies in the health professions[1-3]. During university nursing education, nursing students receive practical curricular knowledge through different learning methods, such as simulations, virtual reality training, or high-fidelity clinical cases[1]. The development of living lab studies is a method that aims to assess aspects such as satisfaction or the usability of a particular medical device, evaluating both qualitative and quantitative characteristics of clinical practice.

The World Health Organization declared that the education and training of healthcare workers is a core of infection prevention [4] and The American Association of Emergency Nursing considers bladder catheterization a high-risk procedure for which providers should periodically demonstrate their competency[5]. The Spanish Association of Urology surveyed 108 nurses at *Hospital Universitario 12 de Octubre (Madrid)* and found that 59.4% were unaware of the urinary catheter management protocol, and only 12.3% had received specific training[6]. This highlights low adherence to guidelines, likely due to poor implementation and limited professional involvement[7].

The most recent efforts to innovate in Foley's catheter design have been focused on modifying them through new coatings[8-10]. T-Control® is a novel silicone catheter featuring an innovative fluid control system that may mitigate CA-UTI risk[11]. Catheter design can influence the risk of CA-UTI and occupational risks. To verify that hypothesis, a previous study of the research group was conducted with first-year Nursing Degree students without prior theoretical or practical knowledge of bladder catheterization, utilizing simulators to compare the conventional Foley-type catheter with the T-Control® catheter[12]. However, the limited number of participants did not permit a statistical evaluation of the differences, leading to the conclusion that there is a need to expand the study to include other university centers and students with prior training in bladder catheterization.

This study aims to assess and analyze bladder catheterization with the T-Control® catheter using simulators, comparing its usability and other additional aspects, such as the workload and satisfaction, with the conventional Foley-type catheter.

Material and methods

Design

A comparative and randomized observational pilot study comparing bladder catheterization using Foley-type and T-Control® catheters with simulators among final-year nursing students who have prior training in bladder catheterization.

Participants

The study sample was composed of 58 final-year nursing students who were enrolled in their undergraduate studies and voluntarily agreed to participate after being informed of the study objectives. Students' recruitment, training, and activities related to the use of the devices were carried out in March 2023. The participants were randomized consecutively, in order of enrollment in the study, and each student carried out the catheterization with only one type of catheter.

The group randomized to the T-Control® catheter received video training on the catheter, emphasizing the differential and innovative element, as well as instructions for its insertion and handling. The students were provided with T-Control® catheters so they could familiarize themselves with the device before the simulation. Next, the students proceeded to the corresponding practice with this catheter system. Likewise, before the simulation, participants who performed the practice with the conventional Foley-type catheter also received video training on bladder catheterization of similar duration to T-Control®.

The inclusion criteria in the study were: 1) Final-year nursing students from the participating center who have been recruited by the professors participating in the study; 2) Students with previous training in bladder catheterization with the conventional Foley-type catheter, acquired during academic training and/or carrying out curricular practices; and 3) Informed consent duly completed and signed. The exclusion criteria were: 1) Students who, once they accept participation, verbalize that they want to abandon the study; 2) Students who at the time of carrying out the study show an unwillingness to participate; 3) Motor disability of the upper limbs; 4) Inability to ambulate autonomously.

Data collection procedure

Once the selection criteria were verified by the research team, informed consent was requested from each student participating in the study. After signing the informed consent, a code was given to the students, and they were randomly assigned to a catheterization system. Before proceeding with the insertion, all students completed the previous NASA-TLX questionnaire to assess the workload they expected from the bladder catheterization. Once they finished the practice, each participant completed the satisfaction questionnaire and a second NASA-TLX questionnaire to evaluate the perceived workload during the simulation carried out.

All the insertions performed by the participants were recorded with a fixed camera in the simulation room so that the evaluators, two expert instructors in clinical simulation with nursing training, could analyze the videos and complete the usability database according to an assessment check-list, which included the number of contaminations and leakages at different stages of the catheterization process: during insertion, urine sample collection, catheter anchoring and connection to the urine collection bag. The analysis of the videos was performed independently by the two evaluators, who were able to watch the recordings as many times as they considered necessary, understanding that all the videos had to be viewed at least once.

Variables and questionnaires

The variables related to the usability of both catheter systems were obtained by visualizing and analyzing the recorded videos of the insertions. The parameters collected were the number of contaminations and the number of accidental spillages. The contaminations were divided by different types according to contaminations of the sterile field, the catheter, the urine sample collection container and the urine collection bag; while the number of accidental spillages was divided according to the moment in which they occurred: during catheter insertion, sample collection, catheter anchoring and bag connection. All this data was analyzed and summarized in a database.

The workload perceived by the participants for both catheter systems was collected through the NASA-TLX questionnaire [13]. This subjective, multidimensional and widely used evaluation tool qualifies the perceived workload to evaluate the effectiveness of a task, system, equipment or other performance aspects. The questionnaire evaluates six different dimensions (mental, physical and temporal demand, performance, effort and frustration) which allow them to be rated on a scale from 1 to 10, with 1 being the lowest score and 10 the highest. The students had to

complete the questionnaire twice, before and after performing the simulation.

Additionally, the satisfaction of the participants for each catheter system was obtained through an *ad hoc* satisfaction questionnaire, which consisted of 20 questions and a free final assessment so that the students could write down any comments, suggestions or observations that they thought appropriate about the device used during the simulation.

The first 11 questions were related to the level of satisfaction and usability of different aspects regarding bladder catheterization, scored on a Likert-type scale from 1 to 5 depending on whether the participants totally disagreed or totally agreed with the statements. 8 questions had a positive connotation (SQ1, SQ2, SQ3, SQ4, SQ5, SQ9, SQ10 and SQ11), so the maximum score considered for them was 5 points (5 = totally agree), while the other 3 questions (SQ6, SQ7 and SQ8) had a negative connotation, so the maximum score considered for them was 1 point (1 = totally disagree). In consequence, the maximum score for the questions with a positive connotation was 40 points (8 questions for a maximum of 5 points each). Therefore, the score obtained for the questions with a positive connotation was added and divided by 40. Whereas, to transform the results of the negative questions into positive ones, the sum of the questions with negative connotations were subtracted 15 points from the total and divided by 15. Subsequently, an average between the positive and negative questions was made and expressed as the mean score for the device analyzed.

$$Satisfaction\ score\ = \left(\frac{(X/40)\ +\ ((15-Y)/15)}{2}\right) * 10$$

Where:

X = Sum of scores for positive questions

Y = Sum of scores for negative questions

40 = Maximum score for positive questions (8 questions x 5 points each)

15 = Maximum score for negative questions (3 questions x 5 points each)

The remaining 9 questions were related to the aspects that, according to the participants, an ideal device for bladder catheterization should include. 8 questions were scored using a Likert-type scale from 1 to 5 depending on whether the participants thought the aspect was not important at all[1] or very important[5] to carry out the bladder catheterization procedure. Finally, in the last question, students were asked if the device they had used during the practice met the expectations of an ideal device, rating it on a scale of 1 to 5 whether they totally disagreed or totally agreed, respectively.

Data analysis

Statistical analysis was performed with the statistical package IBM® SPSS® Statistic Version 28.0. The data has been tabulated and analyzed by using descriptive statistics. The mean, median, and standard deviation have been calculated to summarize quantitative variables. To test if the data had a normal distribution, the Shapiro-Wilk test was conducted. T-Student, Wilcoxon signed-rank or U-Mann-Whitney tests were used, depending on the normality of the data, to assess potential differences between the two studied groups in the variables collected. Cross tables and the chi-square test were used to compare the proportions of the usability section of the study. All tests were two-tailed, and the level of statistical significance was set at 0.05.

Results

Of the 58 final-year nursing students recruited for the study, 10 did not complete any of the questionnaires (NASA-TLX, satisfaction questionnaire or both). Thus, the data collected from these participants was discarded and excluded from the final analysis. Therefore, for the analysis of results, the data of the remaining 48 participants were used, of which 24 performed the simulation with T-Control® and 24 with the conventional Foley-type catheter.

NASA-TLX

Concerning the NASA-TLX questionnaire completed by participants before the urinary catheterization simulation, very

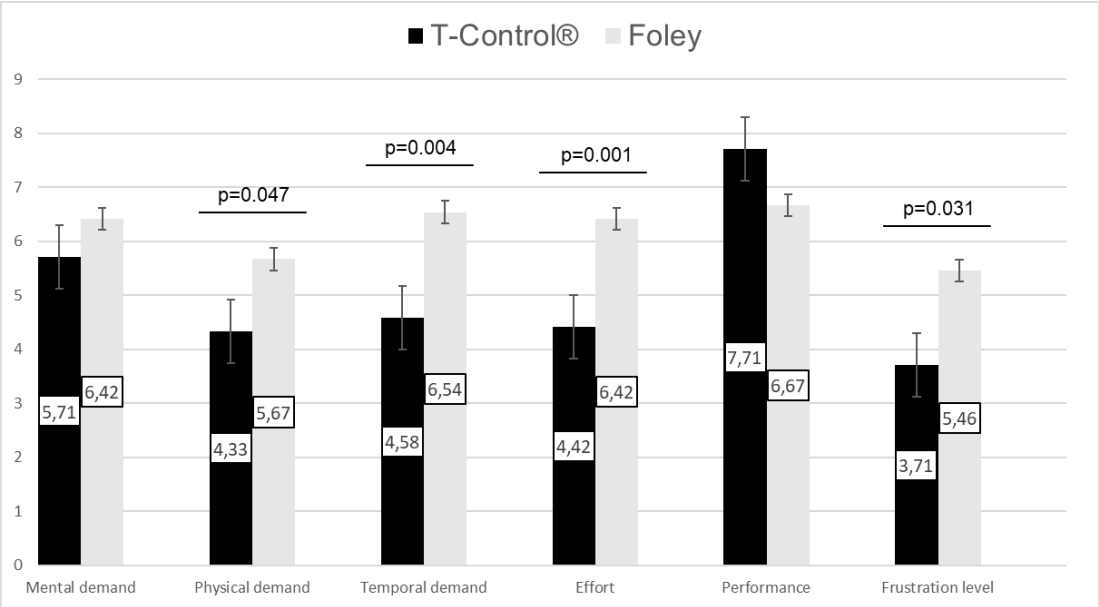

Figure 1. Mean and standard error obtained in the NASA-TLX questionnaire carried out by the participants after performing the practice. Statistical significance is determined at the conventional level of $p < 0.05$.

similar results were obtained between groups, except for the dimensions of performance and frustration level, for which the T-Control® group scored slightly higher than the Foley group (8.67 vs. 7.71 and 5.13 vs. 4.54, respectively). However, no statistically significant differences were found between groups.

When comparing between groups, the results obtained for the NASA-TLX questionnaire fulfilled after performing the simulation, the group that used the conventional Foley-type catheter scored higher in terms of mental (5.71 vs. 6.42), physical (4.33 vs. 5.67) and temporal demand (4.58 vs. 6.54), effort (4.42 vs. 6.42) and frustration (3.71 vs. 5.46), while the group that used T-Control® only obtained higher scores in the performance domain (7.71 vs. 6.67) (Figure 1). Significant statistical differences were observed between the groups in the domains of physical demand (p=0.047), temporal demand (p=0.004), effort (p=0.001), and frustration (p=0.031). That is, compared to the T-Control® group, participants who performed the simulation with the Foley catheter perceived to require greater physical activity and a higher degree of mental and physical effort to obtain their level of performance and felt greater temporal pressure, insecurity, stress, irritation, or dissatisfaction during the simulation.

Additionally, comparing the average scores from the NASA-TLX questionnaires completed by the T-Control® group before and after the simulation revealed that, participants scored higher across all dimensions in the questionnaire administered before the simulation compared to the one completed afterward. However, statistically significant differences were observed only in the domains of mental demand (6.83 vs. 5.71, p=0.047), physical demand (5.54 vs. 4.33, p=0.017), temporal demand (5.96 vs. 4.58, p=0.021), and effort (5.83 vs. 4.42, p=0.002), indicating that, contrary to initial expectations, students experienced less temporal pressure and required less mental and physical effort to achieve their performance levels. When analyzing the Foley-type catheter group, only significant differences were obtained for the performance domain (7.71 vs. 6.67, p-value=0.012), indicating that participants felt less satisfied and less successful with their performance in developing the simulation than they had initially expected.

Satisfaction questionnaire

In the satisfaction questionnaire, participants rated statements reflecting both positive and negative aspects. Scores were computed as detailed in the methodology section, with answers analyzed for positive and negative implications to calculate an overall score for each catheterization system. Table 1 shows the results for both groups of participants regarding the catheter they used during the practice.

Table 1. Mean and standard deviation for Foley and T-Control® groups in the positive and negative connotation questions of the satisfaction questionnaire. Statistically significant differences between groups were determined at the conventional level of $p < 0.05$.

Statements (scores 1 to 5)	Foley		T-Control®		Differences between scorings	p-value
Positive connotation (higher scores mean greater satisfaction)	Mean (N)	SD (σ)	Mean (N)	SD (σ)	(N (%))	
SQ1. I found the device comfortable during the insertion	3.88	1.19	4.75	0.85	0.87 (17.4)	0.001
SQ2. I found the device easy to use	3.83	0.92	4.58	0.83	0.75 (15.0)	0.002
SQ3. I think the device prevents urine leakage during insertion	2.92	1.56	4.71	0.91	1.79 (35.8)	<0.001
SQ4. I have not had difficulties in maintaining the sterility of the process	3.54	1.22	4.17	1.20	0.63 (12.6)	0.042
SQ5. The collection of a urine sample for culture has been easy for me	3.42	1.25	4.83	0.48	1.41 (28.2)	<0.001
SQ9. In general, I have been comfortable using the device	3.5	1.03	4.54	0.93	1.04 (20.8)	<0.001
SQ10. If they gave me a choice in the future, I would choose this catheter for my patients	3.42	1.06	4.67	1.01	1.25 (25.0)	<0.001
SQ11. The procedure was easy for me	3.75	0.94	4.63	0.92	0.88 (17.6)	<0.001
Average of the score for positive statements	**3.53**	**1.15**	**4.61**	**0.89**	**1.08 (21.6)**	
Negative connotation (higher scores mean less satisfaction)	Foley		T-Control®		Differences between scorings (N (%))	p-value
	Mean (N)	SD (σ)	Mean (N)	SD (σ)		
SQ6. There is a greater risk of accidental urine leakage after insertion (involuntary opening, accidental disconnection...)	3.50	1.35	2.21	1.47	1.29 (25.8)	0.004
SQ7. The insertion of the catheter has been stressful for me	2.88	1.26	1.87	1.36	1.01 (20.2)	0.005
SQ8. I would be much better at inserting the catheter with the help of another person	3.88	1.36	2.42	1.44	1.46 (29.2)	0.001
Average of the score for negative statements	**3.42**	**1.33**	**2.16**	**1.43**	**1.26 (25.2)**	
Global satisfaction score (1 to 10)	**Foley**		**T-Control®**		**Differences between scorings (N (%))**	**p-value**
	Mean (N)	**SD (σ)**	**Mean (N)**	**SD (σ)**		
	5.12	**1.47**	**7.44**	**1.78**	**2.32 (23.2)**	<0.001

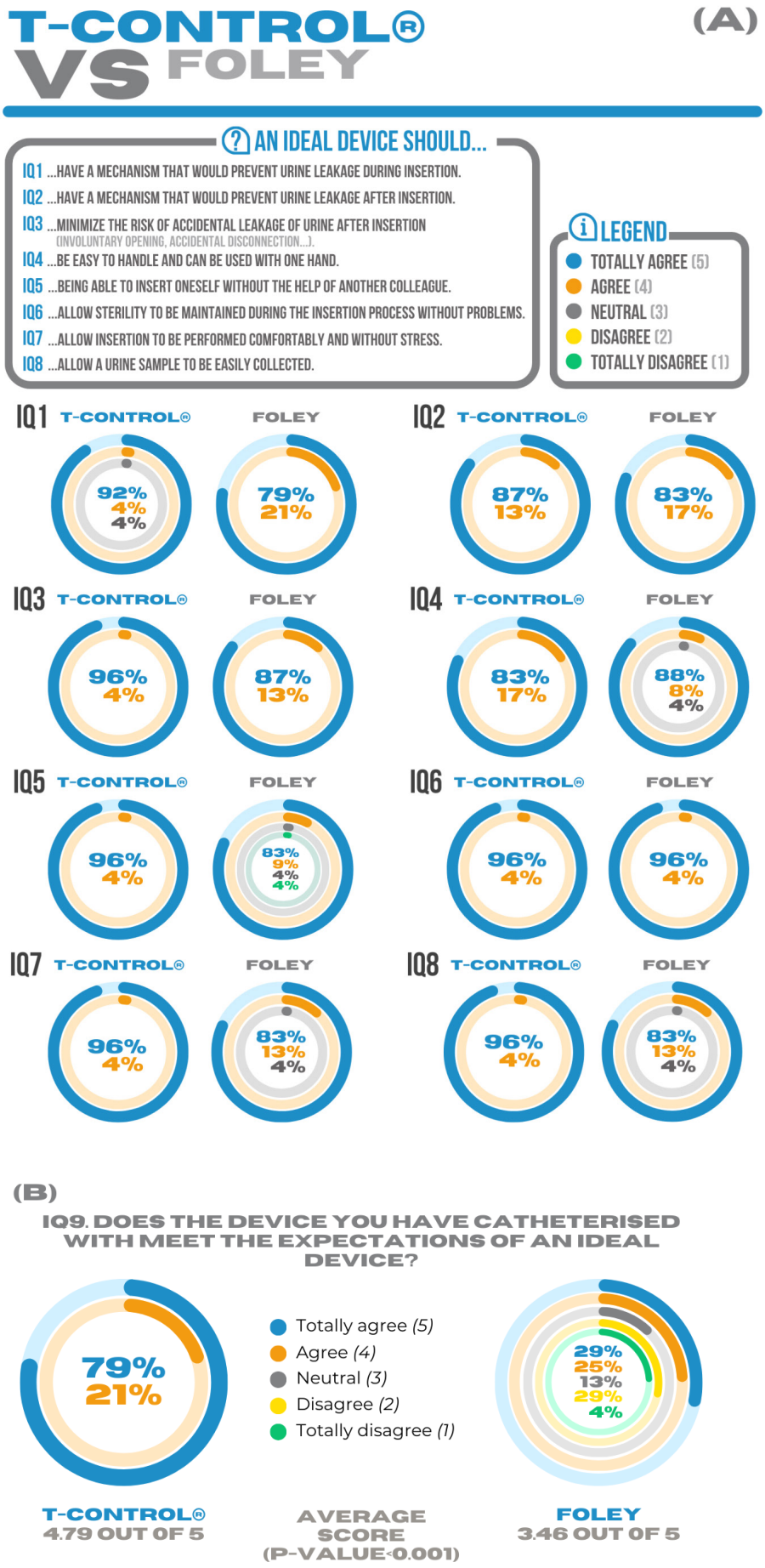

Figure 2. (A) Percentages obtained in questions 1 to 8 of the Ideal device questionnaire. (B) Scores and percentages obtained in question 9 of the ideal device questionnaire. Statistical significance is determined at the conventional level of $p < 0.05$.

Remarkably, T-Control® achieved statistically significantly higher scores on all positive statements compared to the conventional Foley-type catheter. Similarly, T-Control® also recorded statistically significant lower scores on all negatively connoted statements (indicating greater satisfaction). As a result, T-Control® obtained more than 2.3 points of difference (5.12 vs. 7.44) in the calculation of the global satisfaction score (scale of 1 to 10), indicating that the students who carried out the practice with T-Control® were very more satisfied with the device they had used compared to those who had performed the simulation with the conventional Foley catheter.

Ideal device

Both groups rated similarly the importance of the characteristics that an ideal device for bladder catheterization should have (questions from 1 to 8), obtaining scores above 4.67 (on a scale from 1 to 5) in all cases (**Figure 2A**). However, in question 9 of this section, participants using the T-Control® catheter reported that it met the criteria for an ideal device to a significantly greater extent than those using the conventional Foley-type catheter. (4.79 vs. 3.46, respectively; p<0.001). Notably, 33% of the participants who performed the catheterization with the Foley-type catheter disagreed (scores 1 or 2) that the catheter used met the expectations of an ideal device, compared to 0% in the T-Control® group (**Figure 2B**).

Usability

The analysis conducted by two independent experts revealed significant differences between the groups in terms of spillage occurrences during the bladder catheterization simulation. In this sense, participants using the conventional Foley-type catheter experienced a higher incidence of leaks or spillages during the simulation than the group that used the T-Control® catheter, especially during the insertion (79.17% vs. 4.17%) and the collection of the urine sample (54.17% vs. 16.67%), being these differences statistically significant in both cases (p-value<0.001 and p-value=0.007, respectively). However, concerning contamination (sterile field, catheter, urine culture container or urine collection bag), no statistically significant differences were observed between groups.

Discussion

Published studies show that about 15% of CA-UTIs are related to non-aseptic insertions, for instance, due to the contamination of the catheter end before the catheterization[14,15]. Diverse factors contribute to urinary infections but until now, there was only one model of catheter (Foley-type), and the design's potential influence on the onset and progression of infections had not been considered, something to bear in mind since a significant proportion of the participants who used the conventional Foley-type catheter in the present study considered that it did not meet the characteristics of an ideal device. The new design of the innovative device T-Control® has allowed us to compare both devices in terms of usability and workload perceived, healthcare professionals' satisfaction and a determination of the effect that the device's design has.

The results of this study show that participants using the T-Control® catheter reported a more positive and less exhausting experience, perceived as less mentally and physically demanding, causing less stress and frustration. Additionally, the T-Control® group was more satisfied with the device used compared to those who had performed the simulation with the conventional Foley-type catheter.

In this sense, when both groups were asked about the design of the ideal catheter regarding its conditions and characteristics, there was a certain degree of similarity in their responses. However, differences were observed in the participants' opinions about the different catheters tested: while the T-Control® group indicated that the device met the expectations of an ideal device (**Figure 2B**), 33% of the participants in the Foley group expressed disagreement. This could be attributed to the innovative design of T-Control® that allows fluid control, offering a potentially more comfortable and efficient catheterization process. These results are like those obtained in another study conducted with nurses who had a minimum of 3 years of professional experience, and 1 year of experience in bladder catheterization, which showed that 50% of the nurses would exclusively recommend T-Control® in their units, while the other half would recommend it in combination with others[16]. These findings reinforce the importance of considering healthcare professionals' preferences and ease of use in medical device selection, crucial for enhancing patient care and provider satisfaction. Evidence indicates that targeted training, monitoring of adherence, optimization of workloads, and innovative product development could substantially diminish infection rates[17,18].

All body fluids (including urine) should be considered potentially infectious[19,20]. Therefore, the bladder catheterization procedure poses a potential risk not only for the patients but also for healthcare professionals, who may be accidentally exposed to serious and potentially life-threatening pathogens such as COVID-19 or blood-borne viruses in case the urine is accompanied by frank blood, which often occurs[21,22]. Even if the procedure is performed correctly, contamination is a possibility, with the additional risk of spilling the contaminated urine on the patient, surrounding surfaces or on the professional[23]. Moreover, current indwelling catheterization equipment (catheter pack, disposable drapes, linen drapes or kidney dishes) is inadequate in containing urine and blood, posing infection control, occupational health, environmental, and cost challenges[22].

Focusing on preventing urine leaks aligns with healthcare's broader objective to prevent professionals from getting contaminated with patients' urine due to the wide range of diseases that can be transmitted through this fluid[19,20]. In this regard, the analysis of the insertion simulations showed statistically significant differences between groups concerning the occurrence of spillages. The Foley group experienced significantly more incidents, especially during the insertion of the catheter and the collection of the urine sample, indicating that the insertion with T-Control® makes the bladder catheterization procedure easier and safer. In this line, the participants that performed the simulation with T-Control® appreciated features such as ease of handling and comfort during insertion and collection of urine samples, and prevention of urine leaks, expressing a preference for using it with future patients. However, the study highlighted the importance of proficiency in basic nursing techniques to mitigate their impact on the catheter insertion process.

Considering these findings, further research was planned to continue evaluating the disparities between both catheter systems and to address knowledge gaps on nursing techniques related to catheterization.

While simulators provide a controlled learning environment, they may not capture the full complexity of real-life catheterization scenarios. Future research could involve clinical trials in actual healthcare settings to validate these findings. The study population was recruited among final-year nursing students. A larger and more diverse sample size could provide more comprehensive insights. Therefore, future studies might include practicing nurses and other healthcare professionals to understand the broader applicability of these findings.

Continual innovation and improvement in medical devices, driven by user feedback and practical experience, are crucial for advancing patient care and enhancing healthcare provider experiences. These findings are significant for both clinical practice and the development of medical devices, emphasizing the need for user-friendly, efficient, and safe catheterization techniques.

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Conflict of interest

MLG declares being the inventor of T-Control and co-founder of Rethink Medical. CAM, MSM and MMV are employed at Rethink Medical. PRCS, MSM, GF, MFP and MPR declare no conflicts of interest.

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Ethical responsibilities

Protection of people and animals. The authors declare that no experiments involving humans or animals were conducted for this research.

Right to privacy and informed consent. The authors declare that no patient data is included in this article.

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