Teaching and Learning in Nursing 19 (2024) e695–e702

Contents lists available at ScienceDirect

Teaching and Learning in Nursing

journal homepage: www.journals.elsevier.com/teaching-and-learning-in-nursing

Comparative simulated insertion between T-Control® and Foley-type catheter in nursing students with no prior training

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ARTICLE INFO

Article History:
Accepted 21 June 2024

Keywords:
Living Lab
T-Control®
Bladder catheterization
Nursing
Simulation

ABSTRACT

Aims: To simulate the insertion of the new T-Control® urinary catheter with first-year nursing students without previous experience in bladder catheterization and assess the functionality and students' satisfaction compared with the conventional Foley-type catheter.
Material and Methods: A comparative, crossover study was conducted with nursing students. After receiving theoretical training, the participants performed the bladder catheterization with both catheters, the conventional Foley and the T-Control® catheter, on specific mannikins for bladder catheterization. The students assessed both devices by completing an ad hoc satisfaction questionnaire with 33 questions to compare both devices.
Results: T-Control® obtained better scores than the conventional Foley catheter in most individual questions. In the same way, T-Control® was chosen for more than 65% of participants in nine of the eleven statements of the comparative section, all with a positive connotation.
Conclusions: The T-Control® catheter was the best-rated device in both the individual and the comparative questions. Most of the students would choose T-Control® for their future patients. This study has allowed participants to know and practice a technique in nursing work.

Introduction

Urinary catheterization involves inserting a catheter into the bladder through the urethra to facilitate urine drainage. About 15-25% of hospitalized patients require a urinary catheterization at some point (CDC, 2015). Different reviews of studies carried out in a hospital environment show that 13-23% of European patients (Catalán-González & Nuvials-Casals, 2016; Shackley et al., 2017) and 16-24% of American patients (Magill et al., 2014; Patel et al., 2023) are prescribed a urinary catheter.

The hospital areas where a urinary catheter insertion is more frequently performed are the emergency room (2.5-3%) (Manojlovich et al., 2016), the intensive care unit (ICU, 45-79%), the operating room and other surgical (23%) and medical services (17%) (Reportlinker, 2018), mainly in urology and geriatric departments.

The indications for the use of a urinary catheter are diverse: emptying the bladder in case of urinary retention, collecting a sterile urine sample, determining residual urine after spontaneous urination, allowing healing of the urinary tract after surgery, and preventing tension on the pelvic or abdominal wounds. Other possible indications are performing bladder irrigation in case of haematuria or administering medication, strict control of diuresis, preparation before specific surgeries, bladder injuries caused by trauma, keeping skin lesions dry in people with urinary incontinence, and patients who require palliative care (Geng et al., 2024).

A urinary catheter inserted into the bladder is an invasive procedure that can lead to catheter-associated urinary tract infections (CAUTI) (Geng et al., 2024). In Europe, an estimated 4.1 million infections are associated with healthcare, of which between 15 and 20% correspond to Urinary Tract Infections (UTIs) (Álvarez Lerma et al., 2019; Pelling et al., 2019). It is estimated that UTIs can cause up to

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https://doi.org/10.1016/j.teln.2024.06.013

40% of healthcare-associated infections (Duque-Sanchez et al., 2024; Rubi et al., 2022), while the prevalence of hospital-occurred UTIs has been reported in almost 80% of the patients who need a urinary catheterization (Centers for Disease Control and Prevention, 2015; Yu et al., 2020).

Different studies show that 15% of the infections are related to nonaseptic insertions, for instance, due to the contamination of the catheter end before the catheterization (Anderson et al., 2019; Manojlovich et al., 2016;). According to several surveys carried out by the research group, not published yet, with more than 1100 nursing professionals from Spain and Sweden, multiple reasons may explain this fact, such as the difficulty of performing the procedure with a conventional catheter or to carry out the insertion without any assistance.

Apart from the aspects related to the safety of the patients, risks to the health professionals during the management of the catheter should also be considered, such as the frequent spillages of urine or blood. Few articles report these types of accidents, even though various severe diseases can be transmitted with urine, such as Ebola, SARS or COVID-19 (Chan et al., 2021; Puliatti et al., 2020). As the research group was able to verify in the surveys previously mentioned, and not published yet, most professionals would report the spillages if they knew about the transmission of these diseases with urine.

Clinical guidelines based on practical evidence have been developed over the years to standardize the protocols related to the insertion, maintenance, and removal of a urinary catheter to prevent CAUTIs and other safety problems (Bonkat et al., 2023; Lachance & Grobelna, 2019).

The guides and studies related to urinary catheter management and the prevention of UTI support the evidence-based recommendations, including the use of sterile gloves, adequate washing before performing the technique, maintaining the sterile barrier, the intraurethral lubricant administration or the insertion using a noncontact technique. These same studies recommend the improvement and control of the process by health staff and administrations, increasing surveillance and promoting the development of new devices for the prevention of UTI (Jeffery & Mundy, 2020; Patel et al., 2023). Experience shows that most of the infections could be prevented with specific periodic training, adherence control, workload optimization, and innovation in the development of products that pose risks or are easier to use (Reid et al., 2021; Patel et al., 2023). Nevertheless, adherence to the execution and implementation of protocols related to bladder catheterization is extremely low in current clinical practice (Marcone Marchitti & Villa, 2015). Indeed, some recommendations of the guidelines, like the presence of two professionals to carry out the technique aseptically as possible (WOCN, 2016), are rarely followed. This increases the professionals' workload above the assumed optimal level, a risk factor for adverse events (including hospital-acquired infections) and mortality (Fagerström et al., 2018).

University education in nursing nowadays must be focused on the planning and choice of the most efficient teaching tools to achieve specific training objectives, on clinical simulation, and on the creation of scenarios as realistic as possible (Cengiz et al., 2023; Kulakaç et al., 2024). In particular, the insertion of a urethral catheter requires the use of low and high-fidelity devices that simulate the anatomical and manipulation conditions of this type of device (El Hussein and Hakkola, 2023; Koivisto et al., 2024).

Several studies corroborate the positive assessment by students of methods based on simulations (Adams, 2023; Gillis et al., 2019; Kulakaç et al., 2024; Shelley et al., 2023). New and sophisticated simulators are being developed, such as 3D catheterization models, to maximize and create meaningful learning experiences (Cengiz et al., 2023; Gillis et al., 2019; Kulakaç et al., 2024). In this line, different studies have described that students expressed a more positive attitude and higher performance towards training with high-fidelity mannequins (Leigh et al., 2023; Shelley et al., 2023).

As in other countries, bladder catheterization training in Spain is carried out during academic training at the University, through theoretical and practical classes based on simulations in the laboratory. Hence, it is possible that once they graduate, professionals will not practice the technique again until they have to catheterize an actual patient for the first time, months, or even years later. Adherence monitoring is also infrequent (56% or less, depending on country/hospital) (Reid et al., 2021; Spanish Society of Preventive Medicine, Public Health and Hygiene, 2021) and the professionals accumulate errors in their clinical practice that never became addressed (Council Directive 2010/32/EU of the European Parliament, 2010; Jeffery & Mundy, 2020).

T-Control® is a new Foley-type silicone catheter that incorporates an innovative system for active fluid control through a three-position valve integrated into the proximal end of the catheter. The "open" and "closed" positions of the valve, available throughout the whole period of use, allow the control of the urinary flow without the need for the additional accessories required by the standard Foley catheter. The control position, available during the catheter insertion, prevents involuntary urine leakage thanks to a specific in-built membrane. In this way, it is possible to regulate the urine flow and reduce the risk of CAUTI. T-Control® has an additional safety lock to prevent inadvertent or accidental catheter openings. These safety mechanisms allow T-Control®: 1) to keep the system closed and to reduce the risk of accidents due to contamination with biological fluids; 2) to fill the bladder, favoring the conservation of the bladder reflex and tone (Yates, 2016); 3) to reduce pressure injuries of the catheter tip on the bladder mucosa (Holroyd, 2021); 4) to eliminate biofilm and microorganisms, by entrainment, during the intermittently emptying the bladder; 5) to reduce traction accidents and injuries; 6) to totally or partially dispense with the collection bag (Okarska-Napierała et al., 2017); 7) to reduce accidental leaks due to the bag disconnection when mobilizing the patients; 8) to promote a more autonomous and active life of the patient, with the consequent improvement in quality of life (Marcone-Marchitti et al., 2015); 9) to perform the insertion more efficiently by one person.

Given that the development of new products that are easier to handle and involve a reduction in risks could prevent infections, the general objective of this study is to analyze the satisfaction of catheterization with this new and innovative T-control® catheter and compare it with the perceived satisfaction with the conventional Foley-type catheter, which will allow evaluating the usability and advantages that this new design could provide in the catheterization process. The study was conducted with nursing students without prior knowledge or training in bladder catheterization techniques to assess both devices objectively without biases or uncontrolled confounding variables. The objective of this study focuses solely on aspects directly related to the two-bladder catheterization systems analyzed and the perception of the participants' satisfaction level.

Objective

This study aims to analyze and compare the level of satisfaction of first-year nursing students between a T-Control® prototype and the conventional Foley-type catheter, in a Living Lab, an instrument designed to test innovative solutions in real-life conditions with end users. Additionally, the study aims to evaluate the usability and advantages that the new innovative T-Control® catheter can provide.

Methodology

Design

Comparative, crossover study between bladder catheterization with a conventional Foley-type catheter and with the new T-Control® catheter, with first-year nursing students of a Spanish university with no previous knowledge or training on bladder catheterization.

Participants

The study sample comprised first-year nursing students 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 between April and May 2022.

Students who voluntarily decided to participate were registered on a list and were associated with an alphanumeric code to maintain their anonymity. Through this code, the participants were divided into four groups according to the day on which they were going to participate in the study, resulting in 4 participants on the first day, eight participants on the second day and nine participants on both the third and the fourth day. The students randomized on days 1 and 3 were part of the group that began using the conventional Foley-type catheter and then the T-Control® catheter, while the students randomized on days 2 and 4 were part of the group that began using the catheter T-Control® and then the conventional Foley-type catheter. Therefore, both groups performed bladder catheterization with both catheters in a previously established order. It was not possible to use blinding techniques. The sample size of the study was 30 students.

The inclusion criteria in the study were first-year nursing students recruited by the professor participating in the study who had fully completed and signed the consent form. The exclusion criteria were students with prior training in bladder catheterization or students who, after knowing they would participate in the study, had decided to train independently.

Variables and Questionnaires

The satisfaction questionnaire used in the study was developed by the research group based on two previous surveys related to bladder catheterization which were distributed among more than 1,100 Swedish and Spanish health professionals (results not yet published), and in a similar pilot study in which nurses with more than 3 years of experience participated (Molina- Mazón et al., 2023). In addition, the teaching staff in charge of carrying out the theoretical-practical classes that were part of the study, previously reviewed the questionnaire to ensure that it was adapted to the knowledge and skills taught at the university from which the sample of participants were recruited, proceeding to modify it if they considered it necessary.

The variables related to the study were obtained through the completion of this ad hoc satisfaction questionnaire, which consisted of 33 questions: 22 were scored from 1 to 5 depending on whether the participants totally disagreed or totally agreed, while the remaining 11 questions compared the two devices with each other (Annex I). The included questions were related to the satisfaction and usability of different aspects of bladder catheterization. The first 22 questions were assessed using the two devices individually, with 11 questions for each. For the remaining 11 comparative questions, participants had to choose which device best matched the question/statement (Foley-type catheter, T-Control catheter, or both equally).

The 22 questions assessing the devices individually consisted of 11 Likert-type questions (scored from one to five), depending on whether the students totally disagreed or totally agreed. Eight questions had a positive connotation, so their maximum score was five points (5 = totally agree), while the other three had a negative connotation. Hence, the maximum score was one point (1 = totally disagree). Consequently, the maximum score for the questions with a positive connotation was forty points (eight questions for a maximum of five points each). Therefore, the score obtained for the questions with a positive connotation was added and divided by 40. Meanwhile, to transform the results of the negative questions into positive ones, the sum of the questions with negative connotations was subtracted fifteen points from the total and divided by fifteen. Subsequently, an average between the positive and negative questions was made and expressed as the mean score for the device analyzed. For the global evaluation of the questionnaires completed by the participants, an analysis of the total score was carried out according to the values assigned to all the items.

In order to assess the total satisfaction of each participant for each type of catheter, the following formula was followed, taking into account both the questions with positive and negative connotations. A satisfaction score was obtained on a scale from 0 to 10, with 0 being very dissatisfied and ten highly satisfied with the system:

$$\text{Satisfaction score} = ((X/40) + ((15 - Y)/15)2) * 100$$

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)

Data Collection Procedure

Once the research team verified the selection criteria, informed consent was requested from each study participant. After signing the informed consent, a code was given to the students, and they were randomly assigned to an established order according to which catheterization practice they were going to carry out first. All the participants received theoretical and practical training on bladder catheterization procedures.

The theoretical training was carried out by a professor from the university through a master class for the entire group of participants who were going to carry out the simulation, supported by a PowerPoint presentation. Likewise, the practical training took place through a demonstration by the teaching staff of how to carry out the practice, in front of the entire group of students. Next, the students proceeded to carry out the simulation individually and consecutively according to the code that had been assigned to them, without being able to be present in their classmates' simulation. Half first carried out the practice with the Foley-type catheter, and the other half carried out the practice with the T-Control® catheter to later carry out the practice on the other bladder catheterization device. The simulations were carried out in a faculty classroom specially designated for this purpose, with a high-fidelity mannequin for simulation on a stretcher and with the usual available material for this technique, recreating the environment of professional clinical practice.

During the simulation, the participants were not able to receive instructions of any kind from the teaching staff. However, at the end, the teachers held an individualized debriefing with each participant in order to give feedback on their performance and in which the participants were able to resolve doubts and reflect on the technique.

Finally, after the practice, the participants completed a satisfaction questionnaire that included questions about their satisfaction with using both devices (Annex I).

Data Analysis

Statistical analysis was performed with the statistical package IBM® SPSS® Statistic Version 27.0. The data were tabulated and analyzed using descriptive statistics. The mean, median, and standard deviation have been calculated. To test if the data had a normal distribution, the Shapiro-Wilk test was conducted. Due to the non-normality of the data, Wilcoxon signed-rank test was used to assess potential differences between both catheters in perceived satisfaction. All tests were two-tailed, and the level of statistical significance was set at 0.05.

RESULTS

30 first-year nursing students were recruited, and all of them were part of the study's final sample analysis (n=30), given that there was no missing data or participants who decided to withdraw during the study. Of the total participants, 90% (n=27) were women. The following results were obtained from the descriptive analysis of the variables related to completing the questionnaires.

Assessment of the Use of the Two Systems Individually

The value of the score obtained for the eleven questions answered by the participants in the first section of the questionnaire (individual system satisfaction) is summarised in Table 1. Eight of the eleven questions asked for each catheter had a positive connotation (Q1, Q2, Q3, Q4, Q5, Q9, Q10, and Q11), while the three remaining questions had a negative connotation (Q6, Q7, and Q8). In the first case, a higher score on the Likert scale (1-5) implied greater satisfaction with the evaluated system, conventional Foley or T-Control®. On the contrary, in the questions with a negative connotation, a higher score implied a lower satisfaction with the evaluated device.

In most of the answers, for both positive and negative questions, T-Control® obtained better scores than the Foley catheter. The questions in which the greatest statistically significant difference was obtained were Q6 (with a negative connotation), where the scores obtained were 2.10 vs 4.20 (p-value<0.001) for T-Control® and Foley, respectively; and in the question with a positive connotation, Q3 (4.40 vs 2.47; p-value<0.001). Statistically significant differences were also obtained for questions with a positive connotation Q5 (4.33 vs 3.17; p-value=0.005), Q10 (4.03 vs 2.73; p-value=0.012), and Q4, where the scores obtained were 3.27 vs 2.70 (p-value=0.039) for T-Control® and Foley, respectively.

The best-valued questions for the Foley catheter were the questions with positive connotations Q1 (scored 4.03 out of 5) and Q2 (scored 3.60 out of 5), while the worst-valued questions were Q6 (negative connotation, scored negatively 4.20 out of 5) and Q3 (positive connotation, scored 2.47 out of 5). For the T-Control® catheter, the best-valued questions were the questions with positive connotations: Q3 (scored 4.40 out of 5) and Q5 (scored 4.33 out of 5). In contrast, the questions with negative connotations Q8 (scored negatively 2.83 out of 5) and Q7 (scored negatively 2.77 out of 5) were the worst-valued by the participants.

When observing the differences between both systems in the same question/statement, the question with a negative connotation, Q6 obtained the highest score difference between both systems, with 42%, followed by the questions with a positive connotation Q3 and Q10, with a difference of 38.6% and 26%, respectively. However, for the question with a negative connotation Q7 and the question with a positive connotation Q1 these scores differences between systems were minimal, standing at 0.6% and 2.8%, which was confirmed by the p-values obtained in the comparative statistical analysis (p-value=0.972 and p-value= 0.616, respectively). It should be noted that similar difference values were obtained between systems for the questions with a positive connotation (difference of 19.2%) and those with a negative connotation (difference of 18%).

After obtaining the global score for each participant, the mean score among participants was calculated (Table 2). As can be observed in the table, the global satisfaction score for TControl® was higher than the one obtained for the Foley catheter.

The answers included in the first section of the questionnaire (individual system satisfaction) were initially divided into three ranges: a first range with negative responses or in disagreement (Likert scale values 1-2), a second range with neutral responses values (Likert scale 3) and a third range with the responses positive or in agreement (Likert scale values 4-5). The results, expressed in two figures depending on whether the questions had a positive or negative connotation, are shown in Fig. 1.

As can be observed, for positive statements, T-Control® obtained the vast majority of answers (73.75%) in the scale range, indicating agreement (score 4-5), while for the Foley catheter, the answers were more equally distributed between the higher range (score 4-5, 45.41%) and the lower range (score 1-2, 35.83%). The

Table 1
Scoring of Statements Regarding Satisfaction With the Use of Both Systems (1-5 scale)

Statements	Foley		T-Control®		Differences between scorings (%)
Positive connotation (higher scores mean greater satisfaction)	Mean (N)	SD (σ)	Mean (N)	SD (σ)	
Q1. I found the device comfortable during the insertion	4.30	0.93	4.17	0.83	2.8
Q2. I found the device easy to use	3.60	1.10	4.07	0.87	9.4
Q3. I think the device prevents urine leakage during insertion	2.47	1.50	4.40	0.93	38.6
Q4. I have not had difficulties in maintaining the sterility of the process	2.70	1.09	3.27	1.08	11.4
Q5. The collection of a urine sample for culture has been easy for me	3.17	1.37	4.33	0.99	23.2
Q9. In general, I have been comfortable using the device	3.23	1.14	3.90	1.03	13.4
Q10. If they gave me a choice in the future, I would choose this catheter for my patients	2.73	1.51	4.03	1.25	26.0
Q11. The procedure was easy for me	3.30	1.06	3.77	0.82	9.4
Average of the score for positive statements	3.15	0.51	3.99	0.36	19.2
Negative connotation (higher scores mean less satisfaction)	Foley		T-Control®		Differences between scorings (%)
	Mean (N)	SD (σ)	Mean (N)	SD (σ)	
Q6. There is a greater risk of accidental urine leakage after insertion (involuntary opening, accidental disconnection...)	4.20	1.06	2.10	1.35	42.0
Q7. The insertion of the catheter has been stressful for me	2.80	1.45	2.77	1.31	0.6
Q8. I would be much better at inserting the catheter with the help of another person	3.40	1.25	2.83	1.29	11.4
Average of the score for negative statements	3.47	0.70	2.57	0.41	18.0

Table 2
A Global Satisfaction Score was Obtained for Each Catheter

	Global satisfaction score (0-10)	
	Mean	SD
FOLEY	4.69	1.76
T-CONTROL®	6.43	1.79

Table 3
Statements of the Questions of the Questionnaire Delivered

Statements
Q1. *It is the most comfortable for insertion.*
Q2. *Urine sample collection is easier.*
Q3. *It prevents urine leakage during insertion.*
Q4. *It prevents urine leakage after insertion.*
Q5. *I have had no difficulties in maintaining the sterility of the process.*
Q6. *It allows me more time to think about the steps to follow during the procedure.*
Q7. *There is a greater risk of accidental urine leakage after insertion.*
Q8. *The insertion of the catheter has been more stressful for me.*
Q9. *I would be more likely to do well without help.*
Q10. *In general, I have felt comfortable using the device.*
Q11. *If they gave me a choice in the future, I would choose this catheter for my patients.*

results were more equal for the neutral range between Foley and T-Control®.

On the contrary, for the negative statements, opposite results were obtained between the Foley catheter and the T-Control® catheter, since for the first one, the majority of responses (55.55%) were obtained in the range indicating agreement (score 4-5), while for the T-Control® catheter, a very similar result was obtained (52.22%) but in the range that indicated disagreeing (score 1-2) and vice versa.

Comparison Between Catheters

In the second section of the questionnaire (comparative), the participants were asked about eleven statements, which are shown in Table 3. They had to answer which of the devices evaluated best matched the question: Foley catheter, T-Control®, or both catheters equally. Statements Q1, Q2, Q3, Q4, Q5, Q6, Q10 and Q11 had positive connotations while statements Q7, Q8 and Q9 had negative connotations.

The results in percentages are shown in Fig. 2. The results for Foley are represented in blue, while the results for T-Control® are represented in orange. As it can be seen in the orange bars, for 9 of the 11 statements answered, more than 65% of the participants chose T-Control®, especially for Q6 (90%), Q2 (83.3%), Q3 (83.3%), Q4 (83.3%), Q9 (83.3%) and Q11 (83.3%). The Foley catheter was only chosen by the majority of participants in Q7 (86.7%), and in Q8 (56.7%).

Discussion

The aim of this study was to analyze, evaluate and compare in a Living Lab environment the perceived satisfaction of first-year nursing students between two devices for bladder catheterization, the conventional Foley-type catheter and the innovative T-Control® catheter. Bladder catheterization is a common procedure in clinical practice, however, there may be differences in knowledge, attitudes and practices between health professionals from the same institution or even from the same service. These differences may be due to different reasons, whether due to the knowledge and skills acquired during their training stage, the period elapsed from learning to catheterization of a real patient, the frequency with which they perform the technique in their professional performance, the years of experience, the availability of continuing education courses and practices at their institution or the personal desire to continue training in the technique by updating new guides and protocols.

Therefore, to homogenize the sample of participants in terms of their knowledge, attitudes and practices concerning bladder catheterization and avoid biases that could distort the comparison between both devices used in the study, this population was considered the most appropriate, given that all participants started from the lack of both theoretical and practical knowledge of the technique.

Traditional educational courses present several limitations in the field of student preferences and often clash with the demands of professional practice (Zitter et al., 2016), therefore, they could be considered insufficient according to the purpose that they pursue. The continuous and rapid development of technology allows new educational methods, to be integrated more efficiently into theoretical-practical educational programs in higher education. In turn, these new methodologies make it possible to integrate research into education and enhance education with practice.

This study allows us to highlight another relevant aspect that can aim at the evaluation of medical devices in development, in a group of nursing students, providing evaluation aspects different from those of registered health professionals. With this study, it is possible to combine academic aspects during nursing training and the teacher's vision during learning, with specific aspects of the development of health devices, for nursing use, allowing to create a relationship between university nursing teaching and health technological innovation.

In a Living Lab, the end users can participate actively in the research, development, and innovation process. It is an innovative research method that values user perceptions and participation in

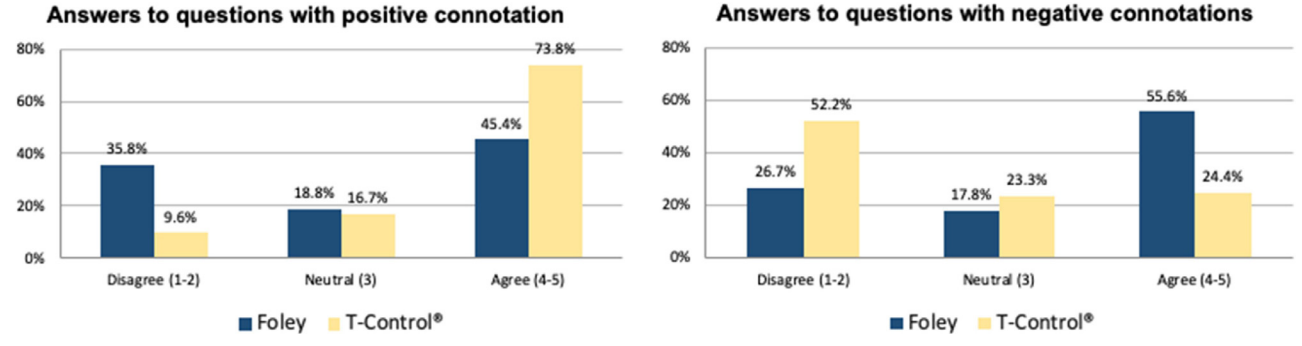

Fig. 1. Comparison of answers obtained in the 3 different ranges of the Likert scale (Disagree, 1-2; Neutral, 3; and Agree, 4-5) for both catheters, Foley-type (in blue) and T-Control® (in orange).

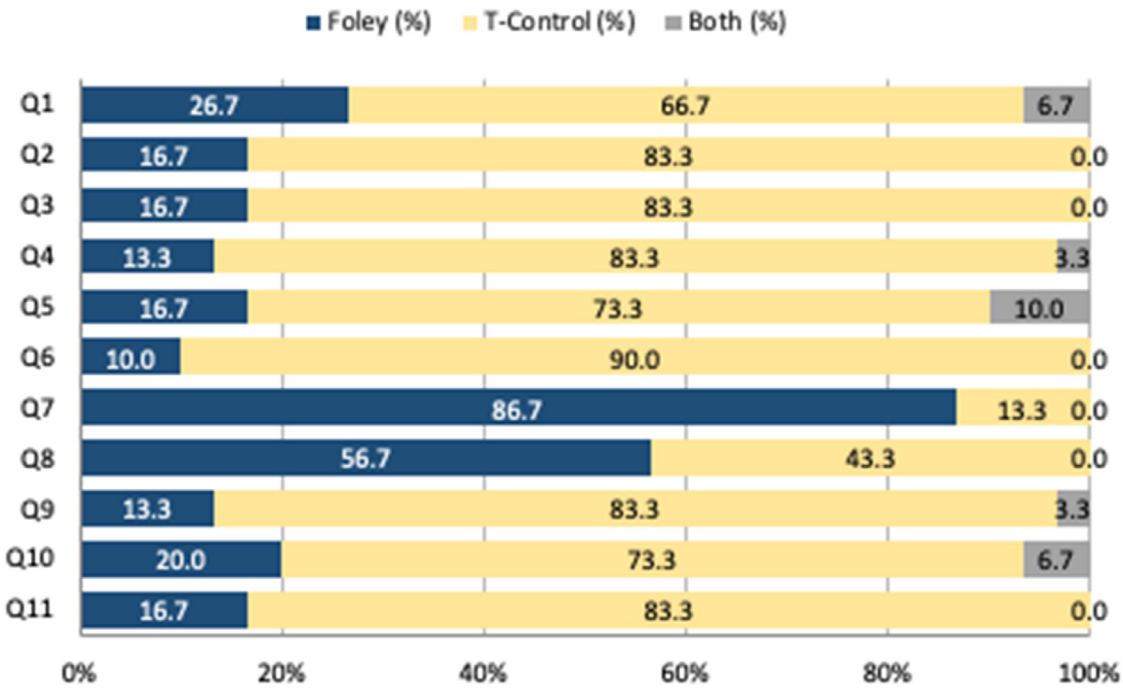

Fig. 2. Results of the comparative questionnaire between Foley-type catheter and T-Control® catheter.

the cocreation of new products and services (Riva-Mossman et al., 2016) and allows companies to get new and innovative ideas directly from end users. However, Living Labs are a relatively new educational tool in higher education and the publications that study their phenomenon and application are recent and limited.(Van den Heuvel et al., 2021).

T-Control® is a new silicone bladder catheter that aims to reduce adverse events associated with bladder catheterization, such as CAUTI or biofilm formation, as well as minimize occupational risks through improved usability during the catheterization process compared to the conventional Foley catheter.

Currently, there is no similar product on the market, however, it could be considered that the functions of its integrated valve at the distal end could be similar to those performed by catheter valves that are currently available as accessories. From the point of view of patient safety, it has been suggested that valve-controlled intermittent emptying of the bladder could limit local inflammatory responses (Lwaleed et al., 2016), maintain its function, capacity and tone (Holroyd, 2021) and reduce the risk of trauma caused by drainage bag and by lifting bladder wall away from the catheter tip (Holroyd, 2021). In addition, it has also been suggested that it could involve a reduction in the risk of infection and biofilm formation. In fact, in a recent in vitro study by the research group in which the formation of biofilm at 3 and 5 days between T-Control® and the conventional Foley-type catheter was compared a notable reduction in biofilm formation was observed in the T-Control® catheter (results not yet published), which could indicate that this new innovative catheter could prevent or delay the formation of E. coli biofilm through its intermittent urine-voiding system, which involves a greater flow of urine that could expel the bacteria, imitating the functioning and natural defenses of the urinary tract.

From the point of view of health professionals, little attention has been paid in the scientific literature to the minimization of occupational risks and ease of use of the devices, factors that could improve adherence to protocols, directly impacting a reduction in risks of adverse events specifically associated with bladder catheterization, generating a safer environment for patients and health professionals, while reducing costs for health systems.

In this Living Lab, first-year students could be trained and perform two bladder catheterization techniques in a natural and realistic environment. Recruiting students without prior knowledge and experience in the technique has allowed totally neutral assessment when comparing both catheters, a conventional Foley-type catheter and a prototype of the new urinary catheter T-Control®.

It is important to note that a simulation mannequin, such as the one used in this study, has its limitations since it only allows evaluation of aspects related to the insertion itself and not those directly related to the catheterized patients, such as catheter obstruction, bladder reflex, or the quality of life, among others. Nevertheless, it is possible to evaluate several aspects related to the insertion process, such as contaminations, the exposure of professionals to biological contaminants, the opinion of the participants regarding the workload related to bladder catheterization, or compare the handling of different types of devices. However, it is also important to highlight that the use of a nonvalidated instrument implies that its feasibility, reliability, validity and sensitivity are not confirmed, which represents a limitation of the study.

In this study, it was observed that the participants showed higher satisfaction with using the TControl® catheter vs the Foley-type catheter. Scoring the catheters individually, the Foley-type catheter was found comfortable during the insertion. In contrast, the T-Control® catheter was found easy to use, as the participants considered it could prevent contamination and urine leakage during insertion and facilitate urine collection. Nevertheless, the insertion with both devices was considered equally stressful, which would make sense considering that it was the first time the students performed the technique.

Regarding the results observed in the comparative study, all the statements with positive connotations were scored higher for the T-Control® catheter. In contrast, the only statement scored higher for the Foley-type catheter was the one regarding the greater risk of accidental urine leakage. According to the answers, T-Control® allows them to think about the steps to follow during the insertion. It is considered better than conventional Foley-type in preventing urine

leakages, both during and after the insertion. Despite the insertion with both catheters being considered stressful, comparing both catheters, a higher percentage of students (56.7% vs 43.3%) chose the insertion with the conventional Foley-type catheter as more stressful.

Additionally, the participants' satisfaction level regarding both catheters was higher for the TControl® catheter since it scored 6.43 out of 10 vs the conventional Foley-type catheter, which obtained 4.69 out of 10. This score agrees with the one obtained in a previous study by the research group with professional nurses, who gave T-Control® a final score of 7.5 out of 10 (Molina- Mazón et al., 2023).

Therefore, the results indicate that the students participating in this study were more satisfied with the catheterization with the T-Control® catheter than with the conventional Foley-type catheter, which is consistent with the fact that most participants (83.3%) would choose TControl® for their future patients. Similarly, in the study previously described with professional nurses, all of them would recommend the use of T-Control® in their departments, alone (54.5%) or in combination with the other systems (45.5%) (Molina- Mazón et al., 2023).

This Living Lab has allowed us to test the insertion of a T-Control® catheter in a simulation mannequin with inexperienced students without prior knowledge of catheterization. The higher level of satisfaction shown for T-Control® highlights the advantages and importance of developing new devices that improve the technique of bladder catheterization, not only to elevate professional satisfaction but also to prevent the appearance of UTI in catheterized patients.

Furthermore, this study would allow in the future being able to analyze by the research group the learning curve in relation to the bladder catheterization technique through the follow-up of the students who participated, yielding possible relevant evidence for educational programs in nursing and nurse education. Taking into account that it is possible that the knowledge and skills acquired during the educational stage are not retained efficiently until the moment of developing the professional practice, precisely due to the period of time that elapses between these two moments, the evaluation of said learning curve could have implications for improving the efficiency of nursing educational programs in order to better prepare future healthcare professionals for their performance in clinical reality.

The cohort of participants recruited for this study does not allow the generalization of results to other types of cohorts. Therefore, this study will be expanded by repeating the methodology in other university centers and with other students, in this case, with previous training in bladder catheterization, which will allow for obtaining more reliable results in terms of septicity and maintenance of sterility.

The use of nursing students with limited previous experience in the use of medical devices allows the evaluation of these devices from an exciting and enriching perspective. In comparison with already nursing professionals who may move away from the recommendations based on evidence due to customs learned in their workplace, it allows an assessment with a theoretical and practical basis only, providing interesting perspectives to the development of new products for clinical practice.

Conclusion

In this research study, the participants had never performed bladder catheterization before and had never used the devices under evaluation, either the Foley-type catheter or the T-Control® catheter.

The students answered questions regarding the devices' positive and negative aspects. TControl® catheter was the best-rated device with greater ease of use, comfort, and better risk control in loss of sterility in bladder catheterization or control in taking urine samples. Total 25 of the 30 students who participated in the simulation (83.3%) would choose the T-Control® catheter to perform bladder catheterization in their patients.

Ethic Considerations

The simulation was approved by the corresponding Ethical Committee (reference: CEIH-2022- 03).

Subjects were identified with an alphanumeric code to guarantee anonymity; the principal investigator only knew the personal data. The data was recorded and kept confidential, not making such information accessible to people outside the study.

Regarding the confidentiality of the data obtained in the study, it is guaranteed that only personal data essential for carrying out the study has been collected. The treatment, communication, and transfer of the participating subjects' data will be adjusted to the provisions of the current Law.

CRediT authorship contribution statement

All the authors have contributed to the manuscript writing and preparation. PRCS, SE, ML and MDH are responsible for the conception of the study and its coordination, whereas PRCS, MS, SE, ML and MDH are responsible for the study design process. PRCS, MM, MS, LCP and ML are responsible for data collection and PRCS, CA, MM, MS and JEHR are responsible for data analysis. PRCS, CA and MM drew up the initial manuscript draft. All authors contributed substantially to the manuscript's revision and approved the final version.

Funding

This study was funded by private funding contributed by Rethink Medical.

Declaration of competing interest

Author Castellano-Santana PR from Universidad de Las Palmas de Gran Canaria declares that he has no conflict of interest.

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Supplementary materials

Supplementary material associated with this article can be found in the online version at doi:10.1016/j.teln.2024.06.013.

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