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Three-way bladder catheter prototype for bladder washing

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Abstract

The main postoperative complications of Transurethral Resection of the Prostate (TURP) are urinary retention by blood clots in the probe and exogenous contamination of the urinary system by manipulation of the healthcare professional when performing the bladder washing technique. The aim of this study was to develop a prototype for keeping the urinary system closed during bladder washes and to measure the internal pressures of the three-way Indwelling Urinary Catheter (IDC) during the bladder washing technique. This was a technological study based on the Rozenfeld's Product Development Process model. Functionality tests were carried out through experiments in a controlled environment in the laboratory. The prototype showed satisfactory results regarding the preservation of the urinary system closed during the bladder washing technique. It was possible to obtain specific pressures from the three-way IDC at three different moments: unobstructed catheter, partially obstructed catheter, and totally obstructed catheter. The results obtained demonstrate that the prototype can represent an innovative tool in the area of urology. It met the project's specifications and preserved the urinary system closed during the bladder washing. Moreover, it reduces the risk of urinary system contamination during the technique manipulation. Therefore, the present study showed that the prototype is fully safe regarding the pressures exerted inside the IDC. There is a need to carry out experimental tests in humans to prove the decrease of urinary tract contamination with the use of this prototype.

Keywords: Transurethral Resection of the Prostate. Nursing care. Inventions. Indwelling Catheters. Therapeutic irrigation.

INTRODUCTION

Benign prostatic hyperplasia is a common clinical condition in the male population from the sixth decade of life onwards. It is directly related to aging and can affect between 50% to 90% of individuals over 60 and 85 years of age, respectively[1,2,3]. Transurethral resection of the prostate (TURP) is the standard treatment of choice in the management of benign obstructions representing 95% of surgeries performed on prostates smaller than 60cc[1,4,5].

In patients undergoing TURP, the use of an indwelling urinary catheter (IDC) in the postoperative period is essential and indispensable since the catheter serves as a support for the urethra after surgery and is generally used in a short-term period. Its insertion after the surgical procedure is intended to promote continuous irrigation and drainage of bladder fluids as well as maintain the urinary tract clear, measure urinary output, control macroscopic hematuria, and monitor urinary obstruction[5,6,7].

Postoperative complications include urinary

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retention due to IDC obstruction (2 to 10%), urinary tract infection (UTI), and bacteriuria (5%), as well as later complications such as erectile dysfunction (4.2%), retrograde ejaculation (75%), urinary incontinence (1%) and urethral or bladder neck stenosis (3%)[8].

After prostate surgery, the guideline is to remove the bladder catheter as soon as possible to reduce the incidence of urinary tract infection, as well as to avoid opening the closed system to preserve the sterility of the urinary content[9].

Patients with postoperative bladder irrigation therapy who present with obstruction of the urinary system in the tube by blood clots require the bladder washing technique. This procedure requires opening the closed urinary system to perform manual clearing, which, despite the use of strict aseptic technique, exposes the urinary tract to external contamination with the environment[10].

When performing the bladder washing technique, the professional who performs it comes into direct contact with blood and urine and may become contaminated with the fluid. Sterile supplies such as cotton gauze, 2% chlorhexidine, sterile glove, sterile field are also used in order to protect the extremities and avoid exogenous contamination as much as possible.

Therefore, keeping the urinary system closed at the time of performing the bladder washing technique can avoid bacterial contamination of the device in its distal portion and, consequently, reduce hospital costs by avoiding prolonged hospitalizations for urinary infections, in addition to reducing the exposure of the healthcare professional to bodily fluids.

The aim of this study was to develop a medium-fidelity prototype for three-way IDC maintaining the principle of the closed urinary system, and to measure the internal pressures of the catheter during the bladder washing technique with the prototype.

METHODS

This is a descriptive and of technological extension study with the materialization of a medium-fidelity prototype a descriptive study and a technological extension study with the construction of the Product Development Process (PDP) were used for the assembly and construction of the prototype, characterized by Rozenfeld.

This process is related to managing the set of activities to develop a product. We defined the planning macro-phase, in which the advantages, disadvantages and the functionality and viability of the product were defined. The development of the product began when this phase was completed.

Informational Project: phase responsible for identifying a set of information called the product's target specifications. These specifications guide the creation of solutions, in addition to providing the basis for the evaluation and decision-making criteria that the product needs.

Conceptual Project: phase responsible for conceptualizing the product through the search, creation, representation, and selection of solutions. The prototype was developed in 2D designs and later in 3D designs on the computer. The purpose was to ensure that the interventions performed on the catheter, such as the technique of bladder washing and the removal of the irrigation equipment were carried out with the urinary system closed at all times.

Preliminary Project: phase responsible for analyzing the optimal number of possible combinations of solutions for the problem in question.

Detailed Project: phase responsible for product development. A prototype was developed with specific parts used for intravenous therapy available on the market: three-way stopcock and closed system connector. The device was attached to the second and third route of the three-way IDC with the aid of Hellermann tape at the ends, which ensured a connection of the materials, keeping the system closed during the interventions in the catheter. The prototype was tested for functionality at the Instituto do Coração, HCFMUSP bioengineering laboratory.

Experimentation: With the device assembled, it was possible to test different pressures exerted inside the three-way IDC and in the compliant balloon that simulated the function of a bladder. The goal of performing the pressure tests is summarized in measuring the pressures exerted inside the catheter and in the compliant balloon. The procedure was carried out during the bladder washing technique; that is to verify if the prototype interfered negatively in some pressure exerted inside the bladder. Measurements were taken at three different moments: unobstructed catheter, partially obstructed catheter, and totally obstructed catheter.

Organization of materials: The following materials were used: silicone compliant balloon; three-way IDC; neutral pressure closed system connectors; three-way stopcock, 60ml luer lock™ syringe; 500 ml bottle of 0.9% saline solution; 250 ml bottles of distilled water; silicone glue; KellyTM clamp; plastic security seals; Edwards DTH4 pressure transducers; four-channel pressure conditioning module and Data Q WinDaq DI-220 acquisition system.

System assembly: The material stand was prepared for the prototype tests. The distal tip of the three-way IDC was glued inside the compliant balloon and filled with 250 ml of 0.9% saline solution. An Edwards pressure transducer was attached to the second port of the bladder catheter to measure the internal pressures of the second lumen of the indwelling urinary catheter. The three-way stopcock and the neutral pressure closed system connector were attached to this route with the help of the Hellermann tape, a security seal. Another pressure transducer was connected to the third port of the indwelling urinary catheter to measure the internal pressure of the compliant balloon. This route is responsible for performing bladder irrigation therapy and a neutral pressure closed system connector was attached to it. The first route responsible for inflating the safety balloon inside the bladder did not undergo any adaptation.

The compliant balloon was filled with 250 ml of 0.9% saline solution (SS) and its hole was sealed with silicone glue to prevent air entry or exit. The compliant flask was placed inside an open container with 100 ml of distilled water. The 60 ml catheter tip syringe was fitted into one of the taps that gave access to the second urinary catheter. Therefore, it was possible to perform the infusion and aspiration of 60 ml of 0.9% saline solution, which simulated the bladder washing technique. In the experimentation laboratory, it was possible to perform the technique of infusion and aspiration of the 60cc syringe plunger, which we named throughout the work as “runs”.

Runs 1 and 2 correspond to 0.9% SS infusion (positive pressure) and run 3 corresponds to 0.9% SS aspiration (negative pressure) simulating the bladder washing technique of this route.

Signal calibration: Two channels of the Data Q WinDaq DI-220 acquisition system were used, which recorded the internal pressures exerted on the second route of the bladder catheter and the internal pressures of the third route of the catheter referring to the compliant balloon. The system performed the automatic detection of pressure values and transformed them into units of millimeters of

mercury (mmHg). 1,000 Hertz was used per channel, which allowed recording up to 1,000 points. A background scale was established to obtain the measurement in the pressure tests in the following conditions: unobstructed catheter, partially obstructed catheter, and totally obstructed catheter, which varied between 0 – 250 mmHg.

Description of the maneuver to obtain measurements: The internal pressures of the device were measured under three different conditions: unobstructed catheter, from which no obstructive intervention was applied in the three-way IDC, partially obstructed catheter, where it was necessary to partially clamp the IDC extension through a Kelly clamp, closing it halfway and decreasing the internal lumen of this route, and a totally obstructed catheter, where the IDC was completely clamped by the Kelly clamp, completely obstructing the internal lumen of the route.

250 ml of 0.9% saline solution was applied inside the compliant silicone balloon to verify if the bladder full of content interferes with the pressures obtained from both the bladder catheter and the compliant balloon.

For each maneuver, two stimuli of 0.9% saline solution runs that lasted 60 seconds (run 1 and run 2) and a 0.9% saline solution aspiration stimulus (run 3) were also performed in the period of 60 seconds.

During the determined time of 60 seconds, the data acquisition system measured several pressures exerted both inside the second urinary catheter and inside the compliant balloon simultaneously.

Data Acquisition System: The data corresponding to the pressures exerted on the three-way IDC were collected and stored on the computer using the WinDaq software. This software allowed for the continuous recording of the pressure values exerted in the system, expressed in mmHg. The WinDaq software calculated the mean corresponding to the stimuli applied to the device and allowed the comparison of pressure results in the three channels.

RESULTS

Informational Project: The following variables were identified: clearing the three-way IDC keeping the system closed at all times, regulating the flow and manual pressure of the bladder washing being safe and ergonomic, avoiding movement restrictions for the patient, and synthesizing the time of procedure and materials used by the nursing team to perform the bladder washing technique.

Conceptual Project: A device model was proposed that would make it possible to perform three-way IDC bladder washing, keeping the entire urinary system closed during the execution of the technique.

Preliminary Project: After several adaptations made to the device, the ideal prototype for bladder irrigation and bladder washing therapy was developed, as shown in Figure 1.

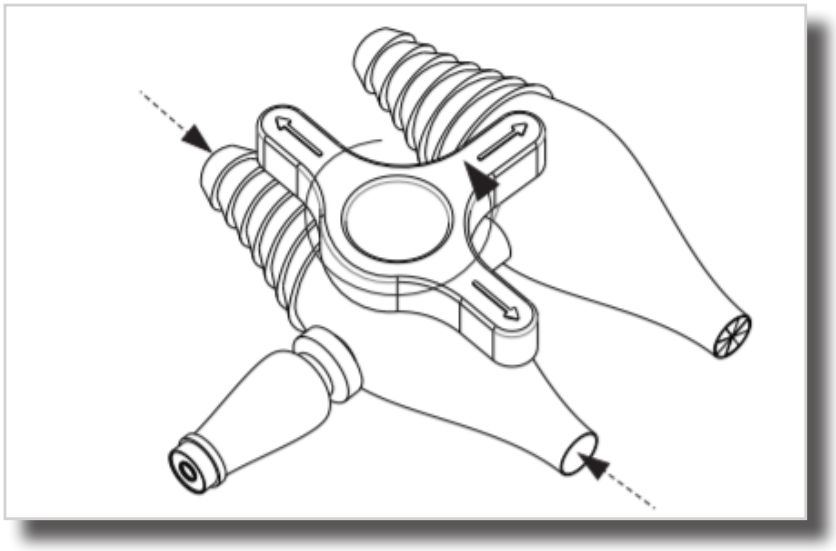

Figure 1 – Layout of the prototype that connects the three-way IDC, the urine collector and the bladder irrigation set.

The device is shaped like a stopcock with a 180-degree rotating switch. The switch is capable of regulating the route that will be manipulated, controlling the opening, closing and direction of the saline infusion in the bladder irrigation, and also capable of controlling the drainage of urine to the urine collection system. The lateral part of the device allows for access to the route responsible for vesical washing (second lumen) through the connection of a 60cc catheter tip syringe. This route keeps the entire IDC urinary system closed during bladder irrigation therapy and during the bladder washing technique.

To perform the functionality tests, there was a small change in the layout compared to the previously idealized design as shown in Figure 2. A minimum viable product (MVP) version was developed which allowed laboratory testing as described below.

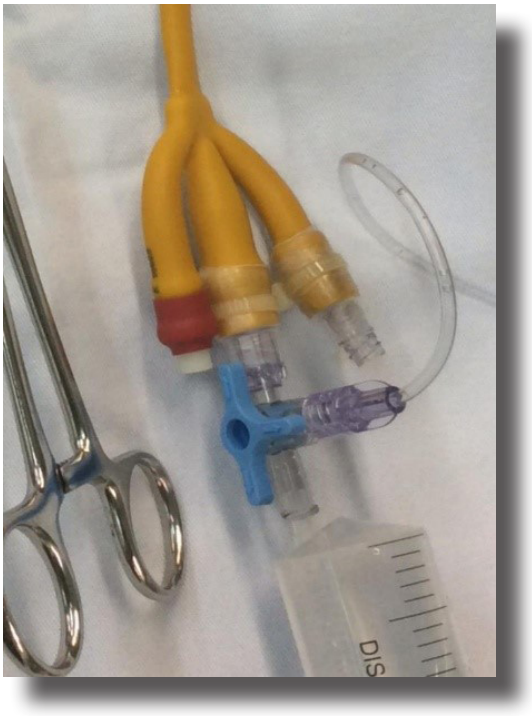

Figure 2 – Prototype developed for functionality tests.

Detailed Project – Functionality Tests: The constructed prototype was used to measure the internal pressures of the IDC in three movements: unobstructed channel Figure 3, partially obstructed Figure 4, and totally obstructed Figure 5.

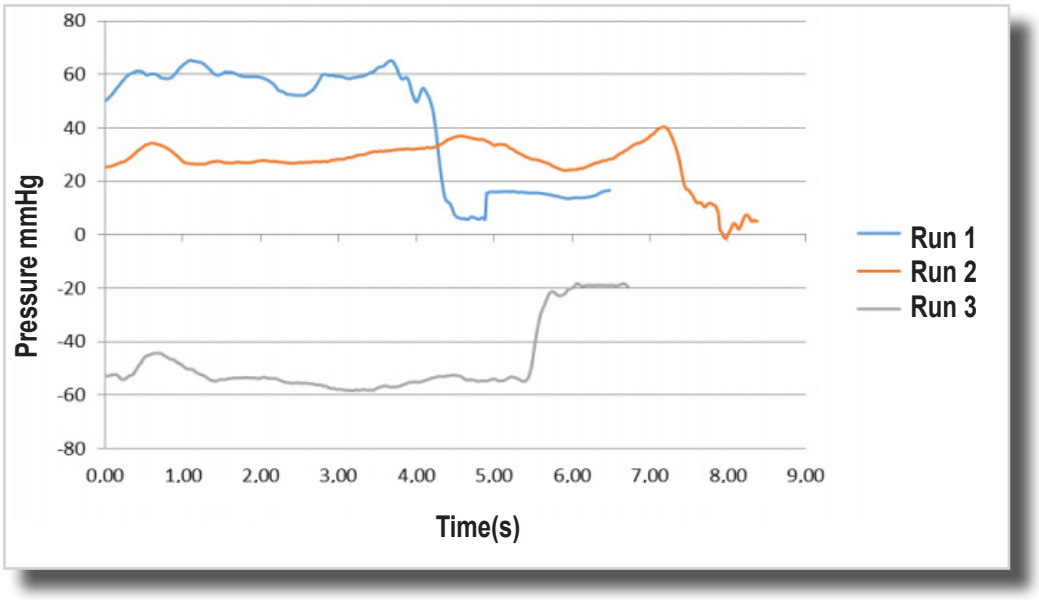

Figure 3 – Internal pressures exerted on the three-way IDC in the bladder washing technique - unobstructed channel.

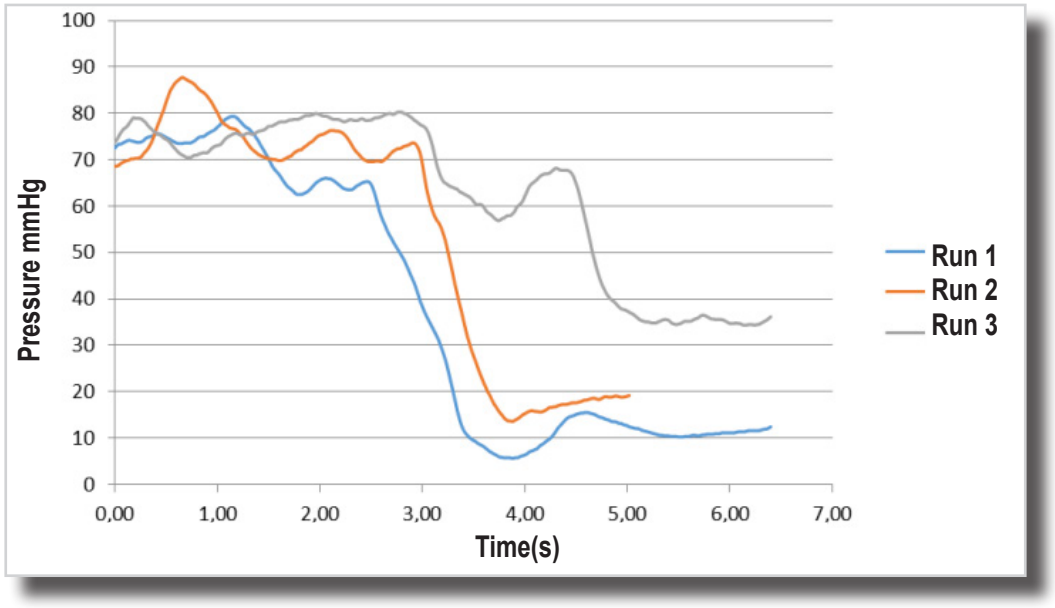

Figure 4 – Internal pressures exerted on the three-way IDC in the bladder washing technique –partially obstructed channel.

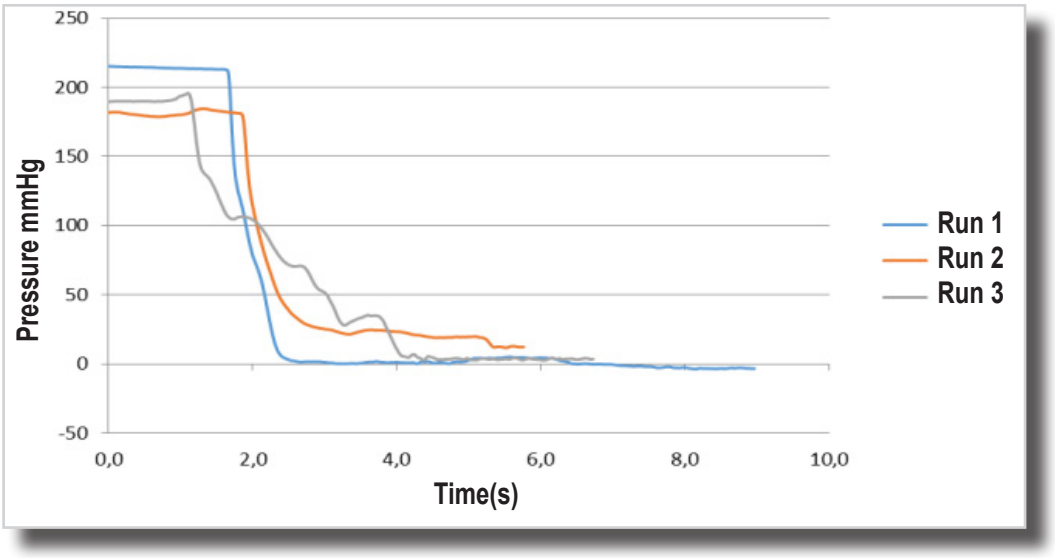

Figure 5 – Internal pressures exerted on the three-way IDC in the bladder washing technique –totally obstructed channel.

The tests with pressures exerted on the bladder catheter's second route are shown in Figure 5.

The maximum pressure exerted on the second IDC route was 111.22 mmHg in 2.99 seconds and the maximum pressure in the balloon was simultaneously 21.58 mmHg, as shown in Figure 6.

A drastic drop in the internal pressure of the catheter was observed in the partially obstructed channel category at the exact moment of unblocking, that is, when the ends of the Kelly clamp of the three-way IDC were fully opened, as shown in Figure 7.

At the exact moment (time=3.12s) of catheter clearance, the maximum pressure exerted on the second IDC route was 70.24 mmHg and the maximum pressure in the balloon was simultaneously 14.63 mmHg.

Figure 8 demonstrates the pressures exerted in the fully obstructed channel category.

At the exact moment (time=0.74s) of catheter clearance, the maximum pressure exerted on the second IDC route was 234.27 mmHg and the maximum pressure in the balloon was simultaneously 13.54 mmHg.

The use of the prototype does not change the flows of bladder irrigation or urinary bladder drainage, allowing a normal functioning of the three-way IDC.

Table 1 – Means of the varying pressures exerted on the unobstructed, partially obstructed, and totally obstructed channel module during the 60-second period.

	Maximum catheter pressure (mmHg)	Maximum balloon pressure (mmHg)	Minimum catheter pressure (mmHg)	Minimum balloon pressure (mmHg)
Unobstructed channel	111	22	9	3
Partially obstructed channel	70	15	13	2
Totally obstructed channel	234	14	70	0.5

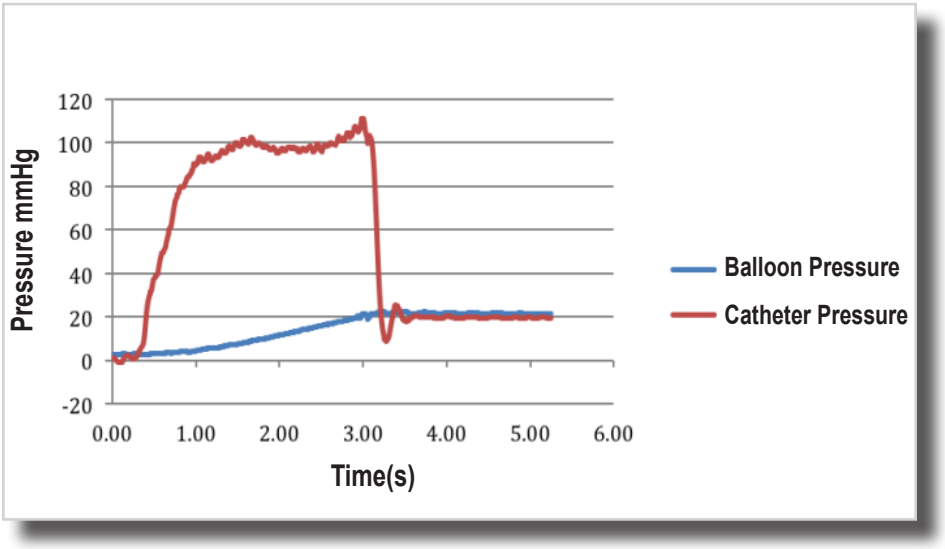

Figure 6 – Cleared Channel – comparison between the internal pressure of the catheter and the internal pressure of the balloon.

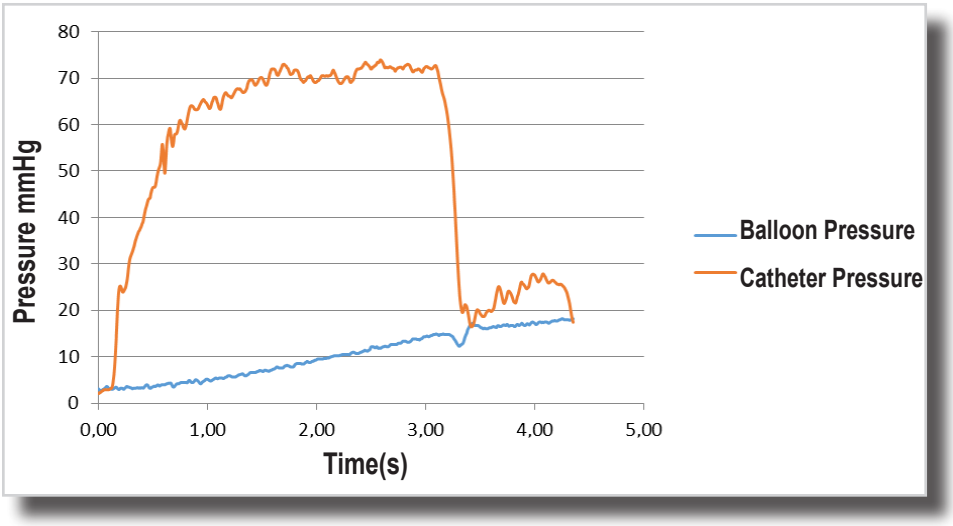

Figure 7 – Partially Obstructed Channel: comparison between the internal pressure of the catheter and the internal pressure of the balloon.

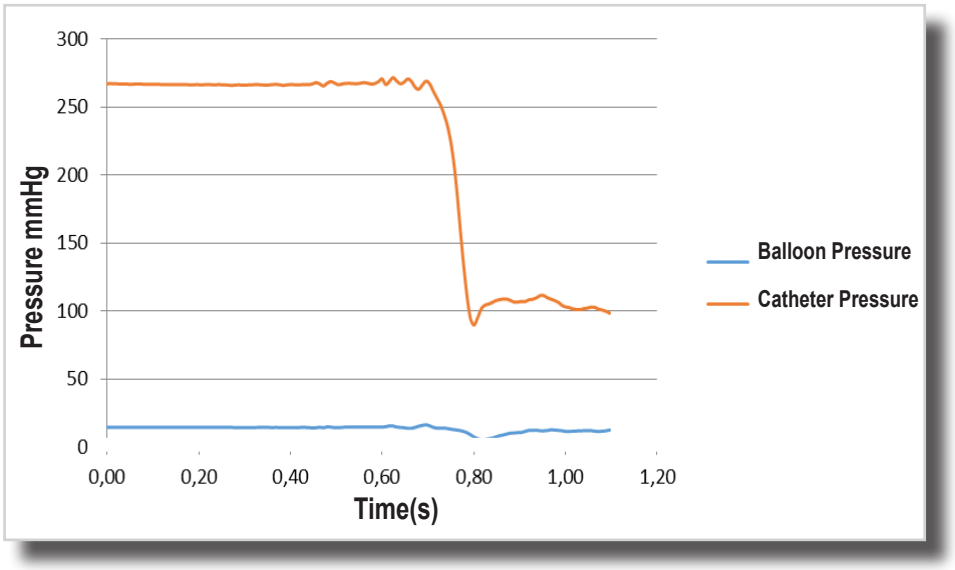

Figure 8 – Totally Obstructed Channel – comparison between the internal pressure of the catheter and the internal pressure of the balloon.

DISCUSSION

The main challenge in the three-way IDC bladder washing technique is the opening of the sterile closed urinary system increasing the risk of contamination of the device by the health professional during the execution of the task.

Mebust reports an 18% complication rate in patients undergoing TURP. The most common were hemorrhage requiring blood transfusion in 3.9%, urinary retention due to obstruction of blood clots in 2 to 10% and culture-documented urinary tract infection in 5%[11,12,13,14].

The respective measurements of pressures in run 3 of Figure 3 are presented in a negative form due to the speed of aspiration of the manual 60cc syringe since the channel does not present resistance in the catheter due to some mechanical obstruction.

The maximum and minimum pressures exerted with the 60cc syringe and the saline solution inside the catheter in the following channel categories: unobstructed, partially obstructed, and totally obstructed showed important variations, as shown in Table 1.

It is observed that when a high manual pressure is exerted on the three-way IDC by the 60cc syringe, the internal pressure of the balloon remains constantly low as shown in Figures 5, 6, and 7 during the three channels: catheter unobstructed, partially obstructed, and totally obstructed.

The bladder is a reservoir that must hold large volumes at low pressures. This is called compliance, and it is extremely important, as it translates the vesical behavior during the storage phase. Impaired bladder compliance can even affect the upper urinary tract. Bladder pressure is measured by cystometry, which in normal conditions range from 0 to 20 cmH2O, which is equivalent to 14.71 mmHg[13].

The results described in Figures 6, 7, and 8 are below the tolerable limit of bladder

compliance capacity. The tests performed followed the pressure values for a compliant bladder, according to data in the literature.

Cystometry allows assessment of bladder capacity, compliance, bladder sensitivity, and detrusor activity. McGuire's study is a classic that shows a high risk of kidney injury when the detrusor pressure reaches 40cm H2O, which is equivalent to 29.42 mmHg. Lower urinary tract obstruction is defined as the presence of a detrusor contraction of high magnitude (pressure) and appropriate duration associated with a low urinary flow[15,16].

In the pressure tests performed in the partially obstructed and totally obstructed channel category, we obtained a high maximum pressure in the second route of the vesical catheter and the internal pressure of the balloon was always low, not exceeding the maximum limit supported by the compliant bladder. No retrograde saline content was observed by the system itself despite having high pressures within the second lumen of the catheter. Right after the moment (time=0.80s) of catheter clearance, the pressure drops drastically in the second IDC route and remains constant inside the balloon.

The pressures exerted on the unobstructed channel category were higher in relation to the partially obstructed channel due to the force exerted on the professional's fingers during the bladder washing technique, which resulted in a higher internal pressure. When there is no obstructing force such as a blood clot preventing the passage of the channel wash, the internal pressures will fluctuate according to the force exerted on the plunger of the 60cc catheter tip syringe.

It was observed that the maximum pressure exerted on the catheter is not the same as that found in the bladder simulated by the compliant balloon, based on the pressure formula: $P = F / A$[17]. The pressure is inversely proportional to the area, that is, the pressure exerted on the inside of the catheter becomes negligible for the bladder, as the vesical area is immensely larger than the internal diameter of the three-way IDC. In this way, the bladder washing procedure can be performed safely without any possibility of causing any injury to the upper urinary tract[18,19,20,21].

According to INCA, we have an incidence of 23,000 prostate and bladder TURP surgeries/year in Brazil, and of these, five percent may have some complication of urinary retention due to clots, requiring manipulation of the closed urinary system with the technique of bladder washing[22].

During this technique, blood and urine fluids come into contact with the external environment, exposing the patient and the professional, which can cause urinary infection, prolonging the length of hospital stay due to the use of antibiotic therapy.

Considering that the length of stay for the treatment of urinary tract infection is seven days, and that the cost of stay/day in the Medical Clinic Unit and Intensive Care Unit varies from R$4,000.00 to R$18,000.00 respectively, with the technology proposed in the prototype, we would have savings ranging from R$33,000,000.00 to R$145,000,000.00 in public health.

The device was developed to avoid the risk of contamination of the closed urinary system during the execution of the bladder washing technique by the healthcare professional. The main advantages of using the prototype compared to the technique traditionally used are described in table 2.

Table 2 – Main advantages of using the prototype compared to the traditional technique of bladder washing.

	Optimization of nursing staff time	Optimization of material resources	Preservation of the Closed Urinary System	Avoids External Contaminations	Decreases Healthcare Professional Exposure to Body Fluids
Prototype	x	x	x	x	x
Bladder Washing Technique	-	-	-	-	-

The prototype brings practicality and biosecurity to professionals who perform the technique of bladder washing as it reduces exposure and contamination to body fluids, in addition to reducing the use of sterile materials used during the technique, optimizing material resources.

The time for the nursing team to perform the technique would also be optimized since the prototype would dispense all bed preparation to receive the breaking of the urinary system.

An advanced search was carried out in the database of the National Institute of Industrial Property with the aim of analyzing the originality of the proposal presented in the prototype and identifying the new technologies applied in the area of urology. The search indicated the lack of any similar devices.

The next steps for the prototype will be to carry out a scale production of the MVP to validate the result in a small experimental group, gathering the experience of the patient and the professional, in addition to comparing the urinary contamination in the two techniques of bladder washing: with and without the prototype through the collection of urine tests. The biggest challenge will be to find licensing partnerships or companies that are interested in technology transfer and transform the prototype into a market product for commercialization in the healthcare sector.

CONCLUSION

The present study enabled the development of a prototype in the form of a device for the preservation of the closed system in the bladder washing. The device has been tested in adverse situations in the condition of an unobstructed, partially obstructed and fully obstructed channel.

According to the analyzes of the mean values of pressures obtained inside the system, resulting from the stimuli exerted on the device, it can be attested that it is fully safe. The prototype developed was also adapted to the conditions of simplicity and low cost, practicality of use and time saving in the technique of bladder washing. The maintenance of the principle of preservation of the closed system was achieved in the tests carried out in the laboratory. However, the prototype needs more specific tests to prove the decrease in the risk of contamination of the closed urinary system in the technique of bladder washing.

CRediT author statement

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All authors have read and agreed to the published version of the manuscript.

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