

Quantification of User and Manufacturer Variabilities in Urinary Catheter Anchoring Balloon Inflation and Mitigation of Variability by Flow Resistance

Niall F. Davis, Eoghan M. Cunnane, Rory C. Mooney, Rustom P. Manecksha, John A. Thornhill, and Michael T. Walsh

OBJECTIVE	To quantify user variability and manufacturer variability in urinary catheter anchoring balloon inflation pressure and to mitigate any significant variance by incorporating flow resistance into the anchoring balloon inflation process.
METHODS	Inflation of a urinary catheter anchoring balloon was performed at atmospheric pressure by different users ($n = 8$) to investigate user variability. A calibrated pressure transducer measured inflation pressures, and a video extensometer measured balloon inflation profiles. Manufacturer variability was investigated by applying constant forces to the plunger of conventional syringes to mimic “heavy-,” “intermediate-,” and “light”-handed users for 3 brands of catheter. Flow restrictors of variable reduced cross-sectional areas were introduced to the outflow of the inflation syringes to investigate the effect of flow resistance on anchoring balloon inflation profiles.
RESULTS	Variations in maximum inflation pressures (range: 75–355 kPa) were observed among the different users. There were no significant differences in maximum inflation pressure between brands at any of the 3 simulated hand forces ($P = .97$). Increasing the flow resistance significantly reduces the applicable inflation pressure of all hand forces ($P < .001$). Specifically, the difference in inflation pressure between heavy- and light-handed forces is reduced from over 405 kPa to under 65 kPa. Introducing flow resistance does not result in a significant difference in inflation pressure between brands ($P = .254$).
CONCLUSION	There is significant user variability in urinary catheter balloon inflation pressure. This variation can be significantly reduced by introducing flow resistance to the inflation technique. UROLOGY 102: 258–263, 2017. © 2016 Elsevier Inc.

The incidence of urethral trauma during catheterization (UC) is low, but this blind procedure performed by health-care practitioners of varying degrees of training is possibly the commonest intervention in hospitalized patients and yields a significant ongoing volume of iatrogenic injuries with serious short- and long-term morbidities, and financial, resource, and medicolegal implications.^{1–3}

Traumatic UC occurs almost exclusively in male patients predisposed by the length and tortuous anatomy of

the male urethra, and in older patients also due to benign prostatic hyperplasia.^{4,5} Iatrogenic urethral trauma can occur during UC by perforation and creation of a “false passage,” or inadvertent balloon inflation within the urethra causing disruption. The incidence of urethral trauma due to inadvertent inflation of the anchoring balloon in the urethra ranges from 0.47% to 0.69%^{1–3} and is significantly higher among junior compared to experienced doctors (73% vs 27%, $P < .05$).⁵ The potential for urethral trauma is exacerbated by significant knowledge deficits among junior doctors regarding the correct technique for safe UC.^{5,6}

Existing strategies aimed at reducing the incidence of traumatic UC by education, supervision, and audit were investigated by Kashefi et al. A nursing education program designed by urology staff was implemented and included urologic anatomy, catheter insertion techniques, and catheter safety protocols.⁷ After 7 months, a statistically significant decrease in risk (by a factor of 4.9) was noted

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From the Department of Urology, Tallaght Hospital, Dublin, Ireland; and the Centre for Applied Biomedical Engineering and Research, School of Engineering, Bernal Institute and the Health Research Institute, University of Limerick, Castletroy, Limerick, Ireland

Address correspondence to: Michael T. Walsh, Ph.D., Centre for Applied Biomedical Engineering and Research (CABER), School of Engineering, Bernal Institute, Health Research Institute (HRI), University of Limerick, Castletroy, Limerick, Ireland. E-mail: michael.walsh@ul.ie

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($P = .006$). A separate 4-year audit of a structured training program demonstrated a significant decrease in the incidence of urethral trauma ($n = 51$ out of 864 in 2007 [6%] vs $n = 29$ out of 725 in 2011 [4%]; $P < .05$).³ These educational strategies are encouraging but time consuming, costly, and clearly not adequately effective.

The risk of iatrogenic urethral perforation by false passage may be reduced in certain clinical scenarios by the use of Coude tip catheters, catheter introducers, flexible guide wires, or silicone leaders, but these technologies are not applicable in routine practice. Likewise, a definitive but simple and cost-effective technology that minimizes the potential for operator error during the balloon inflation process is required.^{1,8,9} Any such technological advances would complement the educational approach to prevent what can be a very serious patient harm.

We previously investigated urethral diametric strain and maximum anchoring balloon inflation pressure thresholds as parameters for preventing urethral trauma during UC in porcine and cadaver models. Our findings demonstrate that a urethral diametric strain $>40\%$ or a maximum anchoring balloon inflation pressure >150 kPa can cause urethral injury during the UC process. Based on these parameters, we designed a safety valve that activates at the urethral injury threshold pressure of 150 kPa.¹ A limitation of this novel approach is the potential for the safety valve to activate when the anchoring balloon is correctly positioned in the urinary bladder due to “heavy-handed” operators applying excessive hand force to the syringe plunger, resulting in a “false positive.” This would prevent complete anchoring balloon inflation in the bladder as the syringe fluid is decanted through the syringe valve and therefore renders the UC balloon inflation step of the procedure ineffective. Furthermore, manufacturer variability, due to variations in anchoring balloon design, may also result in activation of the safety mechanism in a false-positive environment during inflation. Based on these potential

variables, the objective of the present study was to quantify user and manufacturer variabilities during urinary catheter anchoring balloon inflation. Our secondary objective was to mitigate any significant variability by investigating the concept of incorporating “flow resistance” during the anchoring balloon inflation process.

METHODS

Overview of Experimental Design

All materials were obtained from the Centre for Applied Biomedical Engineering and Research, Limerick, Ireland, unless indicated. User variability during anchoring balloon inflation was measured by having users inflate the anchoring balloon at atmospheric pressure to mimic intravesical pressures ($n = 8$). An experimental rig with a calibrated pressure transducer was used to measure inflation pressures and a video extensometer was used to accurately characterize the anchoring balloon inflation profile (Fig. 1A). A second experimental rig was constructed to investigate manufacturer variability during anchoring balloon inflation with 3 different catheter brands (referred to as brands 1, 2, and 3) (Fig. 1B). Constant forces were applied to the plungers of conventional commercially available 10-mL syringes to mimic “light-,” “intermediate-,” and “heavy-handed” users.⁶ The primary end point of the study was to quantify user and manufacturer anchoring balloon inflation variabilities and also to investigate the concept of incorporating flow resistance during the anchoring balloon inflation process to mitigate any significant variability.

Construction of Experimental Rigs

Figure 1A shows a schematic of the experimental setup used to investigate user variability in commercially available urinary catheters. A 10-mL syringe (BD Plastipak; Becton, Dickinson & Company, Franklin Lakes, NJ) was arranged in series with a 10-bar pressure transducer (General Electric,

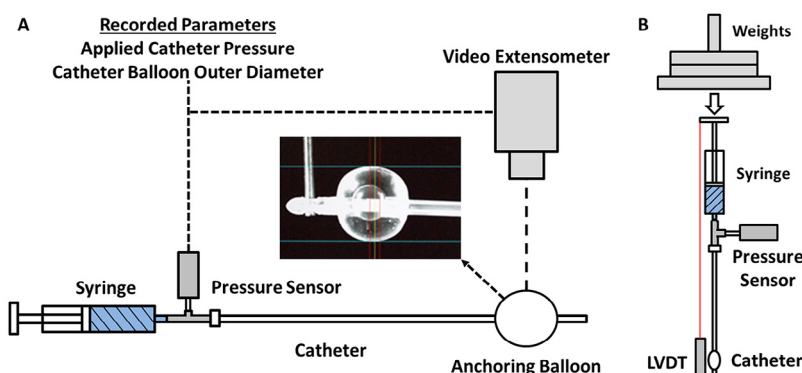


Figure 1. (A) Simplified schematic of the experimental rig constructed to measure the dependence of anchoring balloon inflation pressures on user variability. Pressure and inflation profiles generated by users were measured during anchoring balloon inflation. The pressure applied and the volumes of saline instilled were recorded using the pressure sensor and the video extensometer, respectively. (B) Simplified schematic of the experimental rig constructed to investigate manufacturer variability and flow resistance. The apparatus applies constant force to the system by allowing weights to descend on the syringe plunger. The pressure applied and the volume of saline administered are recorded using the pressure sensor and the LVDT, respectively. LVDT, linear variable differential transformer. (Color version available online.)

Fairfield, CT) to register the pressure generated by each user during anchoring balloon inflation (Fig. 1A). The inflation profile of the anchoring balloon during inflation was monitored using a video extensometer (Messphysik, Furstenfeld, Austria) (Fig. 1A, inset). This experimental setup recorded changes in anchoring balloon inflation pressure and volume with time.

In a second experimental setup, a constant force was applied to the syringe plunger using a custom-built experimental rig (Fig. 1B). The rig consisted of supported weights that descended due to gravity during testing. Varying the applied weights allowed for the hand forces of light-, intermediate-, and heavy-handed operators to be simulated.¹⁰ The volume of saline instilled into the anchoring balloon was recorded by measuring the depression of the syringe plunger with a linear variable differential transformer (Omron, Hoofddorp, The Netherlands) (Fig. 1B). This experimental setup investigated the inflation pressure profiles of the anchoring balloons of 3 urinary catheter brands under constant simulated hand force without the influence of user variability.

Investigating User Variability

The anchoring balloons of 12-French silicone catheters were inflated by health-care professionals at atmospheric pressure to mimic intravesical pressure using standard 10-mL syringes prefilled with sterile water ($n = 8$, 4 males and 4 females). The volume of saline instilled during inflation and the time to inflation were recorded. Changes in inflation pressure and instilled volume over time were measured with the experimental setup described in the section “Construction of Experimental Rigs.”

Investigating Manufacturer Variability

The anchoring balloon inflation profiles of 3 commercially available 12-French catheter brands (ie, brands 1, 2, and 3) were investigated. Standard 10-mL syringes, prefilled with sterile water, were subjected to constant forces by applying calibrated weights (3.5, 7.5, and 11.5 kg) to the syringe plungers (Fig. 1B). These weights descended due to gravity and generated hand forces designed to mimic light- (34 N), intermediate- (74 N), and heavy (113 N)-handed users.¹⁰ An equation relating maximum handgrip force to upper limb location was used to derive this range of representative forces.¹¹ The pressure transducer was used to measure inflation pressure and the linear variable differential transformer recorded the volume of sterile water dispensed from each syringe using the second experimental setup described in the section “Construction of Experimental Rigs.” Each experiment was performed in triplicate.

Investigating the Concept of Incorporating Flow Resistance to Mitigate User and Manufacturer Variabilities

A flow-resistance technique was introduced to control the anchoring balloon inflation profile. Anchoring balloons were inflated at atmospheric pressure under constant forces

designed to mimic light-, intermediate-, and heavy-handed users using the second experimental setup described in the section “Construction of Experimental Rigs.” Flow resistance was regulated by connecting flow restrictors with variable reduced cross-sectional areas (CSAs) to the outflow of each 10-mL syringe. The CSAs of each flow restrictor were 0.2, 0.15, 0.1, and 0.05 mm². These restrictors were designed to standardize flow rate during the anchoring balloon inflation process.

Statistical Analysis

Data were expressed as mean \pm standard deviation. The normality of the data was examined using Shapiro-Wilk tests and all data sets were found to be normally distributed. Therefore, 1-way analysis of variance with post hoc Bonferroni correction was used to compare across groups. Retrospective power analysis was conducted on groups to examine the effect of manufacturer variability on anchoring balloon inflation pressure. Differences were considered significant at $P < .05$ (SPSS 16.0 for Windows; SPSS Inc., Chicago, IL).

RESULTS

User Variability

Figure 2A illustrates the pressure-volume inflation profile and mean flow rates during anchoring balloon inflation at atmospheric pressure by different users ($n = 8$). These values approximate to the pressure-volume inflation profile of the anchoring balloon within the urinary bladder. Widespread variations in maximum inflation pressures (range: 75–355 kPa) and mean flow rates (range: 19.94–69.08 mL/min) were observed. Furthermore, half of the examined users generated maximum inflation pressures greater than 150 kPa. These users would have therefore triggered a false positive when using the aforementioned safety valve and rendered the UC procedure ineffective.

Manufacturer Variability

The mean maximum anchoring balloon inflation pressures for each catheter brand at the constant simulated hand forces of 34, 74, and 113 N are shown in Figure 2B and Table 1. There are no significant differences between the maximum inflation pressures of each brand at any of the simulated hand forces ($P = .97$). Although the power of the present study is relatively low (0.06), increasing the sample size by a factor of 10 would not increase the power to an acceptable level due to the low effect size (0.03).¹² Therefore, under the controlled simulated hand force experiments conducted in the present study, the effect of manufacturer variability on anchoring balloon inflation pressure was considered nonsignificant. Manufacturer variability can therefore be considered negligible. However, maximum inflation pressures for all simulated hand forces were above 150 kPa. This finding indicates that inflating the anchoring balloon of urinary catheters with a “light” hand force or greater would generate a false positive when using the aforementioned safety valve and would render the UC procedure ineffective.

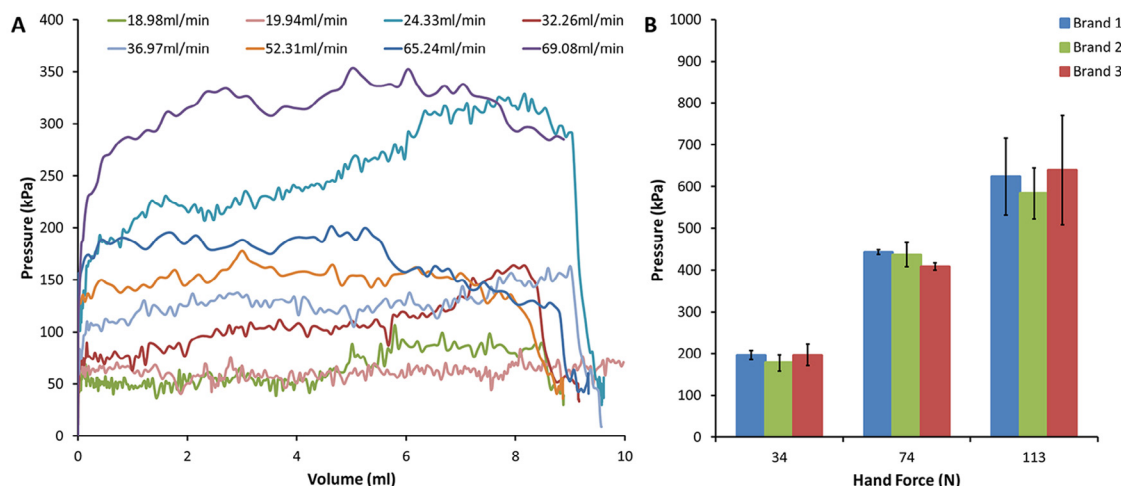


Figure 2. (A) User variability for a normal anchoring balloon inflation at atmospheric pressure mimicking the urinary bladder ($n = 8$). **(B)** Maximum inflation pressures for 3 brands of urinary catheter at 3 simulated hand forces. There is no significant difference in maximum inflation pressure between brands at any of the 3 simulated hand forces ($P = .97$). (Color version available online.)

Table 1. Mean maximum inflation pressures \pm standard deviation for 3 catheter brands under constant forces with and without flow resistance

		Maximum Inflation Pressure (kPa)		
Applied Force (N)		Brand 1	Brand 2	Brand 3
No flow resistance	34	196.08 \pm 10.96	177.98 \pm 19.65	196.87 \pm 25.95
	74	443.25 \pm 5.9	436.75 \pm 129.4	407.95 \pm 8.45
	113	623.89 \pm 92	583.91 \pm 60.49	639.27 \pm 131.22
Flow resistor measuring 0.05 mm ²	34	66.18 \pm 0.4	70.06 \pm 10.54	77.69 \pm 1.09
	74	92.49 \pm 7.56	110.99 \pm 12.53	95.65 \pm 8.61
	113	104.61 \pm 3.36	129.88 \pm 5.88	103.84 \pm 3.83

The applied constant forces mimicked “light-” (34 N), “intermediate-” (74 N), and “heavy” (113 N)-handed operators during UC.⁶ Mean maximum inflation pressures were not significantly different between brands at any simulated hand force in the absence of flow resistance ($P = .97$) or with a flow resistor measuring 0.05 mm² ($P = .254$).

Effects of Flow Resistance on User and Manufacturer Variabilities

A flow-resistance approach was introduced to limit anchoring balloon inflation pressure by placing flow restrictors on the syringe outflow with CSAs ranging from 0.2 to 0.05 mm². Figure 3 demonstrates the effects of increasing flow resistance on inflation pressures and time when applying constant simulated hand forces. Increasing the flow resistance by reducing the CSA of the syringe outflow from 0.2 to 0.05 mm² significantly reduces the applicable anchoring balloon inflation pressure of all simulated hand forces ($P < .001$). Specifically, the difference in mean maximum inflation pressures between heavy- and light-handed users is reduced from over 405 kPa with no flow restriction to under 65 kPa with a flow restriction measuring 0.05 mm². This highlights the mitigating effect that flow resistance has on anchoring balloon inflation user variability. Furthermore, introducing a flow restrictor measuring 0.05 mm² does not result in a significant difference in anchoring balloon inflation pressure between catheter brands ($P = .254$, power = 0.28; Table 1).

The application of the progressively increasing flow resistance also reduces maximum anchoring balloon inflation

pressure for all users to under 150 kPa (Fig. 3A). These values are lower than the previously defined threshold pressure of 150 kPa that results in urethral trauma.¹ All users could therefore operate the aforementioned safety valve without generating a false-positive response. The time to fully inflate the anchoring balloon increased considerably with increasing flow resistance. Specifically, decreasing the CSA of the syringe outflow from 0.2 to 0.05 mm² caused an increase in inflation time of approximately 14, 12, and 7 seconds for light-, intermediate-, and heavy-handed users, respectively (Fig. 3B).

DISCUSSION

Millions of UC procedures are performed annually and urethral trauma caused by inadvertent inflation of the anchoring balloon in the urethra represents a potentially preventable source of iatrogenic injury in hospitalized patients. Furthermore, the incidence of iatrogenic urethral trauma may be under-reported due to inadequate documentation and auditing among health-care professionals managing this patient cohort.^{2,4,7} In the present study, we investigated user and manufacturer variabilities during urinary catheter

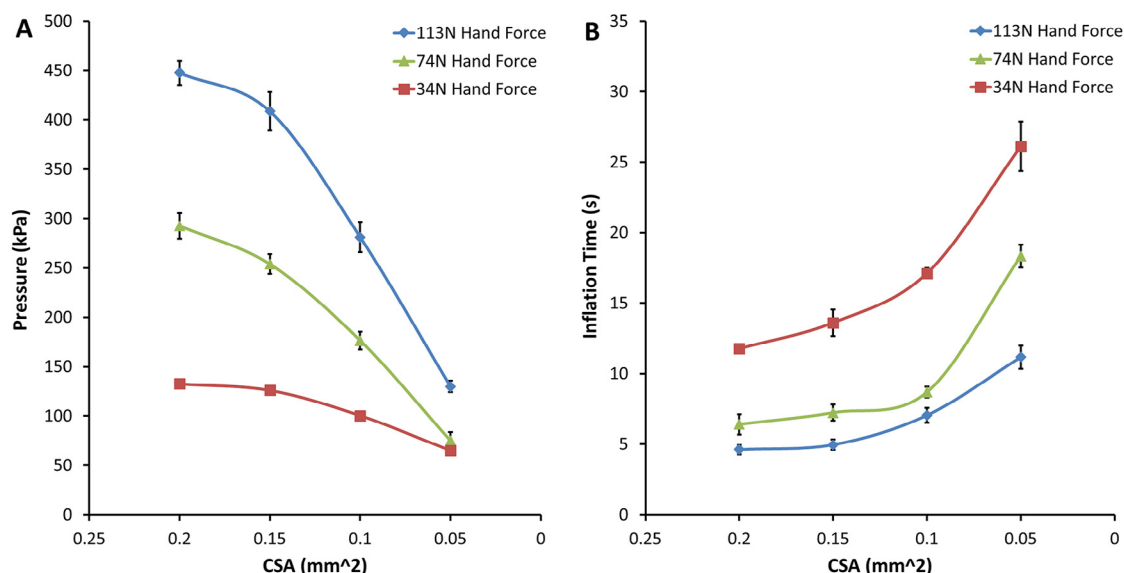


Figure 3. Pressure and inflation time vs flow resistance for the “light” (34 N), “intermediate” (74N), and “heavy” (113N) simulated hand forces. **(A)** Flow restrictors were placed on the syringe outflow with CSAs ranging from 0.2 to 0.05 mm² and constant forces were applied. Reducing the CSA from 0.2 to 0.05 mm² causes a significant decrease in maximum inflation pressure at each hand force ($P < .001$). **(B)** Balloon inflation was completed within a time frame of 5-27 seconds depending on the force applied by the user and the CSA of the flow restrictor. CSA, cross-sectional area. (Color version available online.)

anchoring balloon inflation. Although no significant manufacture variance was observed, considerable user variability exists, which made it impossible to effectively implement a safety valve to reduce the incidence of iatrogenic injury. However, applying flow resistance to the anchoring balloon inflation process reduces the maximum inflation pressures of all users to values below the safety threshold of 150 kPa for urethral trauma. This therefore allows for the implementation of the previously described safety valve to eliminate the risk of iatrogenic injury secondary to inadvertent anchoring balloon inflation in the urethra.¹

The flow restrictor presented in the present study limits and regulates inflation pressures regardless of the hand force applied to the plunger by the user. This finding has important clinical implications. First, mitigating user variability standardizes the anchoring balloon inflation process and allows for a steady and safe inflation profile regardless of the user. Second, flow resistance prevents the potential for activation of a safety mechanism in a false-positive environment. Urethral rupture occurs when >150 kPa inflation pressure is applied to the anchoring balloon and safety mechanisms have been introduced to activate at this threshold pressure, thereby preventing urethral trauma due to inadvertent anchoring balloon inflation in the urethra.¹ However, our initial findings demonstrate that light-, intermediate-, and heavy-handed users apply forces that produce inflation pressures >150 kPa when the anchoring balloon is correctly positioned in the urinary bladder. This approach gives rise to the potential for activation of the aforementioned safety valve despite being correctly positioned in the urinary bladder. Our subsequent findings demonstrate that flow resistance prevents this

false-positive phenomenon from occurring as anchoring balloon inflation pressures remained consistently <150 kPa when flow resistance was introduced. Finally, the extended inflation time required is not excessive considering the potential benefits of this approach.

One prospective study demonstrated that the additional cost of managing 37 iatrogenic urethral injuries (26 [70%] of which occurred due to anchoring balloon inflation in the urethra) was €335,377 over a 6-month period in an institution where approximately 11,000 UCs are performed annually.⁴ This technological solution priced at €5 per device that eliminates 70% of these iatrogenic injuries (those caused by anchoring balloon inflation in the urethra) would save almost 90% of the costs incurred by this preventable morbidity. Such a solution could combine flow restrictors with the existing safety valve technology to act as an auxiliary device that attaches distally to the syringe and proximally to the urinary catheter, therefore leaving both existing technologies unaltered. This cost-effective solution gains even greater importance when the long-term morbidity and financial and medicolegal aspects of iatrogenic urethral trauma secondary to UC are considered.

CONCLUSION

Inadvertent inflation of a urinary catheter’s anchoring balloon in the urethra is a persistent and preventable cause of morbidity in clinical practice. The present study identifies significant user variability in anchoring balloon inflation with the potential to cause urethral trauma as clinicians can easily breach the urethral rupture pressure

of 150 kPa during UC. Mitigating this user variability reduces anchoring balloon inflation pressures to values that are below the safe resistance levels offered by the urethra and also allows for the implementation of the previously described safety valve to prevent urethral trauma due to inadvertent inflation of the anchoring balloon in the urethra.

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