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

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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 ■■: ■■–■■, 2016. © 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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(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,

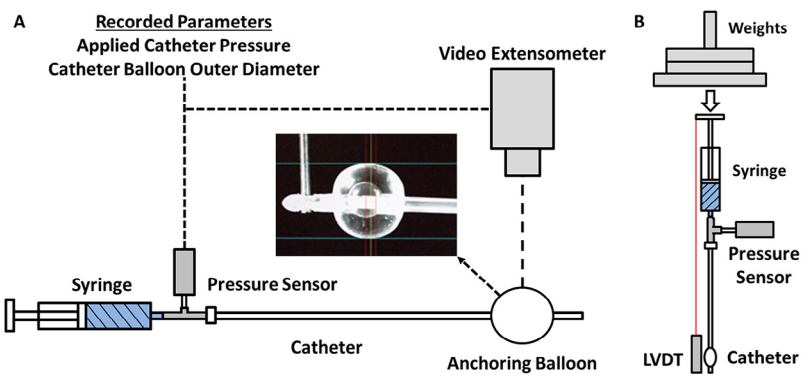

Figure 1. **(A)** Simplified schematic of the experimental rig constructed to measure the dependence of anchoring balloon inflation pressures on user variability. Pressure and inflation profiles generated by users were measured during anchoring balloon inflation. The pressure applied and the volumes 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.)