Preventing Urethral Trauma from Inadvertent Inflation of Catheter Balloon in the Urethra during Catheterization: Evaluation of a Novel Safety Syringe after Correlating Trauma with Urethral Distension and Catheter Balloon Pressure

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Abbreviations and Acronyms

UC = urethral catheterization

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Purpose: We investigated urethral diametric strain and threshold maximum inflation pressure for rupture during inadvertent inflation of a catheter anchoring balloon in the urethra. In addition, we evaluated a novel safety device to prevent trauma based on these parameters.

Materials and Methods: Inflation of a urethral catheter anchoring balloon was performed in the bulbar urethra of 21 ex vivo porcine models using 16Fr catheters. Urethral trauma was assessed with retrograde urethrography. Urethral rupture was correlated with internal urethral diametric strain and maximal urethral pressure threshold values in kPa. Urethral catheters were then inflated in the bulbar urethras of 7 fresh male cadavers using a standard syringe and a prototype syringe. The plunger of the standard syringe was depressed until opposing resistance pressure generated by the urethra prevented further inflation of the anchoring balloon. The plunger of the prototype safety syringe was depressed until sterile water in the syringe decanted through an activated safety threshold pressure valve.

Results: Retrograde urethrography demonstrated that porcine urethral rupture consistently occurred at an internal urethral diametric strain greater than 40% and a maximum inflation pressure greater than 150 kPa. The mean ± SD maximum human urethral threshold inflation pressure required to activate the safety prototype syringe pressure valve was 153 ± 3 kPa. In comparison, maximum inflation pressure was significantly greater using the standard syringe than the activated prototype syringe (mean 452 ± 188 kPa, p <0.001).

Conclusions: Internal urethral diametric strain and threshold maximum inflation pressures are important parameters for designing a safer urethral catheter system with lower intrinsic threshold inflation pressures.

Key Words: urethra, catheterization, iatrogenic injury, rupture, instrumentation

Urethral catheterization is a routine task that is frequently performed in health care settings. Almost 25% of hospitalized patients are catheterized during their inpatient stay.[1] The estimated incidence of iatrogenic catheter related urethral injury is 0.3% to 3% but this may underrepresent the true

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incidence.[2,3] Urethral injury typically occurs in men when the catheter anchoring balloon is inadvertently inflated in the urethra.[4] Short-term complications can include pain, bleeding and acute urinary retention. Urethral rupture can lead to the long-term complication of urethral stricture disease and may require urethral reconstruction in severe cases.[5] Dobrowolski et al reported that approximately a third of urethral injuries occur from traumatic urethral catheterization.[6]

Although iatrogenic complications from UC are well described, to our knowledge there are no studies demonstrating urethral strain thresholds for rupture during inadvertent inflation of a catheter balloon in a patient urethra. The objective of the current study was to explore the relationship between urethral distension, urethral rupture and catheter inflation pressures during urethral catheterization in an ex vivo porcine model. Secondary objectives were to design a safe urethral catheter system that cannot cause urethral trauma despite inadvertent balloon inflation in the urethra. We also aimed to determine the maximum inflation pressure that can be applied to the urethra using a standard catheter syringe, evaluate interoperator variability during the catheter inflation process and compare steady rate balloon inflation with manual balloon inflation.

MATERIALS AND METHODS

Overview of Experimental Design

Fresh porcine urethras were obtained from a commercial abattoir in Ballylanders, Limerick, Ireland, and maintained ex vivo. Ethical approval for ex vivo tissue study and cadaver testing was approved by the University of Limerick, Ireland and the RCSI (Royal College of Surgeons Ireland) ethics approval process. All other materials were obtained from the Centre for Applied Biomedical Engineering Research unless indicated.

The anchoring balloons of urethral catheters were intentionally inflated in the bulbar urethra of each porcine urethra. Retrograde urethrography was performed on each traumatized urethra to determine the relationship between urethral distension and trauma/rupture after traumatic urethral balloon inflation.

Subsequently urethral catheters were inflated in the bulbar urethra of 7 fresh male cadavers with an age of 21 to 90 years. Maximum urethral pressure testing with a standard catheter syringe was determined by measuring pressure values in kPa until opposing resistance pressure generated by the urethra prevented further inflation of the anchoring balloon after depressing the syringe plunger. A novel prototype syringe with a safety valve was developed to prevent over inflation of the catheter anchoring balloon in the urethra during the catheterization process. A syringe pump (Harvard Apparatus, Hollister, Massachusetts) was used to examine the effect of constant flow rate balloon inflation in cadaveric urethras.

Porcine Testing

Preparation of porcine urethras. A total of 21 porcine urethras were acquired from male porcine models at age 7 months immediately after sacrifice, transported to the laboratory on ice and frozen in phosphate buffer solution at −20C for 1 week.[7,8] Urethral samples were prepared by maintaining the bulbous cavernosum musculature. The proximal urethra was ligated adjacent to the bladder neck proximal to the prostate. During the experimental process each urethra was equilibrated to room temperature in phosphate buffered saline and maintained in an organ bath and heated to 37C prior to testing. Before urethral catheterization each catheter anchoring balloon was inflated at atmospheric pressures in room air to serve as a control and pressure volume curves were recorded in 10 preparations.

UC of porcine urethras. Urethral catheter inflation was performed using standard 16Fr Coloplast™ urethral catheters in 21 preparations. The catheter anchoring balloon was inflated in the bulbar urethra with sterile water using a standard 10 ml syringe and syringe pump at a rate of 30 ml per minute. The volume of water instilled during inflation ranged from 1 to 10 ml (table 1). Urethral diameter variability was mitigated by normalizing the internal diametric stretch of each sample to the original diameter at the site of inflation (fig. 1). After inflation of the desired amount of saline in the balloon pressure was recorded using a transducer (SensorTechnics UK, Rugby, United Kingdom). Urethral trauma was then assessed with retrograde urethrography.

Retrograde urethrography to assess urethral trauma. The anchoring balloon of the misplaced urethral catheter was deflated and removed before retrograde urethrography. A second urethral catheter, also 16Fr, was inserted in the urethral meatus. Barium sulfide contrast medium (Rakem, Bury, United Kingdom) was instilled

Table 1. *Volume inflated in catheter balloon in 21 urethral samples, and resulting internal diametric strain and balloon/urethral pressure*

Vol (ml)	% Max Internal Diametric Strain	Max Pressure (kPa)
1A	25	92
1B	3	64
1C	16	74
2A	21	112
2B	43	90
2C	14	140
3A	21	119
3B	6	120
3C	14	97
4A	26	212
4B	38	206
4C	19	175
5A	21	256
5B	46	183
5C	12	166
6A	136	448
6B	30	191
8A	90	229
8B	65	187
10A	107	309
10B	102	292

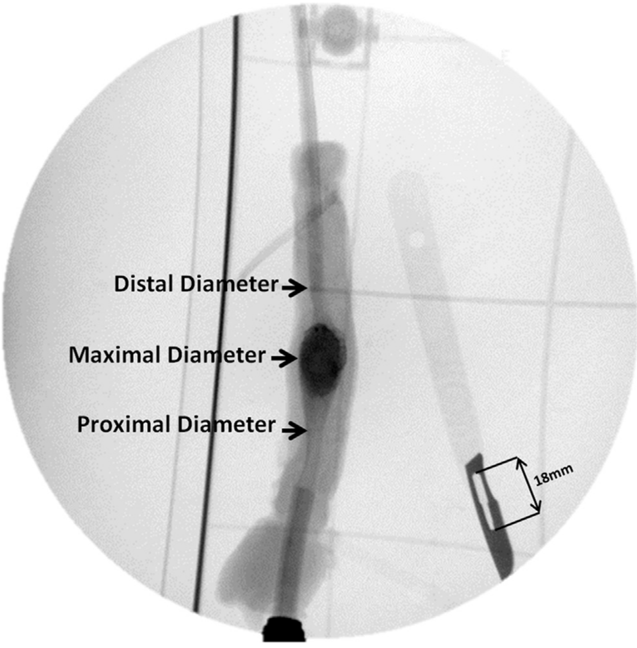

Figure 1. Retrograde urethrogram shows location of bulbar urethral diametric measurements. Internal urethral diametric strain was calculated by averaging urethra luminal diameter proximal and distal to traumatized site and maximum luminal diameter at traumatized site. Scalpel served as known dimension to scale measurements taken from image.

through the catheter drainage channel using the syringe pump apparatus. Contrast medium was instilled. A valve was ligated around the urethra at the bladder neck proximal to the prostate to prevent contrast extravasation from the proximal luminal end.

Traumatized urethras were imaged with plain x-ray using a Ziehm Vision R Fluoroscope (Ziehm Imaging, Orlando, Florida) at 6 angles covering a 90-degree rotation. The maximum pressure in the system was recorded with a pressure transducer. The internal urethral diametric strain was calculated by averaging the urethra luminal diameter proximal and distal to the traumatized site and the maximum luminal diameter at the traumatized site using the formula, internal urethral diametric strain = ?d/d × 100%, where ?d = maximum urethral diameter − average urethral diameter and d represents average urethral diameter (fig. 1).

Contrast material was instilled in a control sample to demonstrate that instillation of contrast medium during urethrography alone did not contribute to any urethral trauma. Thus, any trauma demonstrated on urethrography was solely the result of prior balloon expansion in the urethra.

Calibrating urethral luminal diameter. The diameter of each urethral lumen was measured using ImageJ (http://imagej.nih.gov/ij/), which records accurate measurements from imported images. Initially a scale is set using a reference measurement of a known length from the imported image. In the current study a scalpel with known measurements was included in every radiological image and used as a reference (fig. 1).

Cadaver Testing

Prototype safety valve. Three brands of 16Fr silicone transurethral catheters were lubricated and inserted in the bulbar urethra of 7 cadavers. Position in the bulbar urethra was confirmed by palpation. Sterile water (10 ml) was used to attempt to fill the catheter anchoring balloon in the urethra with a standard 10 ml syringe. Three units of brand 1 were inserted in 3 cadavers, 2 units of brand 2 were inserted in 2 cadavers and 2 units of brand 3 were inserted in the remaining 2 cadavers. Each urethral catheter was inflated 3 times by each of 2 urology trainees using the prototype syringe. During syringe testing the plunger of the prototype was depressed by each physician until water in the syringe decanted through an activated safety pressure valve (switching pressure: 150 kPa) connected to a pressure transducer (GE, Little Chalfont, United Kingdom) (fig. 2). Resistance pressure and volume of sterile water administered in the anchoring balloon were recorded at this point. The testing process was repeated until each trainee had performed 3 urethral catheter inflations to ensure that the safety valve reliably activated during each inflation and the brand of catheter (ie manufacturer variability) did not inhibit the activation process.

Maximum pressure. Following prototype testing each urethral catheter was inflated 1 additional time using a standard commercial syringe. The plunger of the standard syringe was depressed by the 2 trainees until resistance pressure generated by the cadaver urethra prevented further inflation. Pressure in kPa at this point was recorded as maximum inflation pressure.

Constant flow rate. A flow resistance technique was designed for the prototype syringe in an effort to control the inflation profile of the catheter and eliminate potential user variability during the inflation process. A urethral

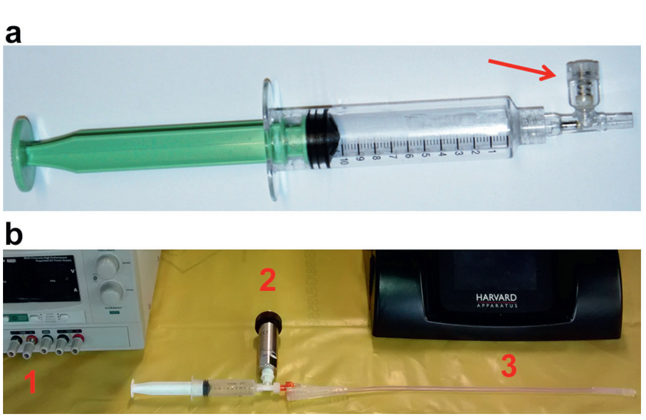

Figure 2. *a*, prototype syringe used to determine urethral resistance pressure. Safety valve (arrow) is activated at threshold resistance pressure, allowing fluid to vent out of activated valve. *b*, experimental setup comprises power supply (*1*), standard syringe, catheter and pressure transducer system (*2*) and syringe pump (*3*). During testing prototype syringe plunger was depressed by each physician until water in syringe decanted through activated pressure valve connected to pressure transducer.

catheter was inserted in the bulbar urethra of 1 cadaver. The anchoring balloon was inflated at a constant flow rate of 30 ml per minute initially using the prototype syringe. The inflation process was repeated using a standard syringe and inflation pressure profiles were compared between the syringes.

Statistical Analysis

Statistical analysis was performed by the Student t-test with unequal variances for pairwise comparisons between groups. Differences were considered significant at $p < 0.05$ using SPSS®, version 16.0 for Windows®.

RESULTS

Porcine Testing

Control inflation pressures. Pressure volume curves to inflate the catheter anchoring balloon at atmospheric pressures in room air at a constant flow rate were measured in 10 preparations (fig. 3). These curves served as controls to compare with anchoring balloons inflated in porcine urethras. They approximated the pressure volume behavior of the catheter anchoring balloon in the bladder. Widespread variations in anchoring balloon material properties were noted in response to increasing volumes during the inflation process (range 60 to 130 kPa after instilling 1 ml saline).

Mitigating urethral diameter variability. The variable internal luminal diameter between porcine urethras was also measured (fig. 4). In sample A instillation of approximately 3 ml saline was required before contact occurred between porcine urethral tissue and the catheter anchoring balloon. However, only approximately 1 ml saline was required in sample B. Consequently urethral rupture occurred after infusing approximately 6 ml saline in sample A compared to approximately 5 ml in sample B. Variations in internal urethral diameter prevented a reliable correlation between the volume of infused fluid required for urethral rupture. Table 1 shows the volume of infused fluid correlated with urethral diametric strain values obtained from retrograde urethrography and the maximum recorded inflation pressure for each individual urethra at indicated volumes. Again the volume of fluid infused correlated poorly with internal diametric strain due to urethral diameter variability. For example, infusing 6 ml saline in the anchoring balloon resulted in 136% strain in 1 urethra compared to 30% strain in another at an identical volume. However, correlating urethral trauma with internal urethral diametric strain mitigated internal urethral diameter variability and produced results

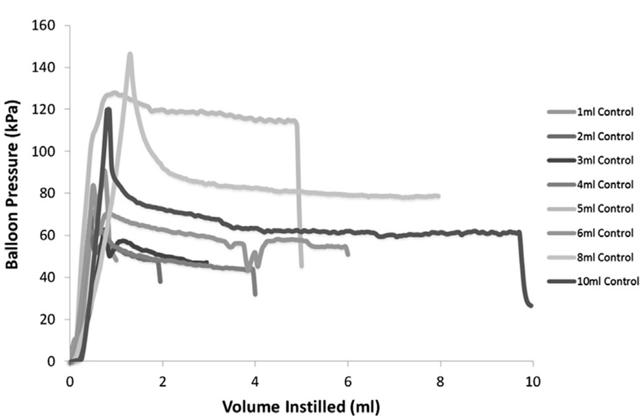

Figure 3. Pressure volume relationships of anchoring balloons of urethral catheters inflated at atmospheric pressure and not inserted in animal model. Pressure approximated pressure achieved when catheter balloon was inflated in 10 bladders. Each anchoring balloon was inflated with graduated volume of saline. Maximum pressure required for inflation ranged from 70 to 150 kPa. Pressure relationships differed for each catheter due to volume of fluid instilled. Overall unimodal pressure increase was followed by stable sustained pressure pattern. As anchoring balloon distended, pressure decreased and balloon material offered less resistance to expansion.

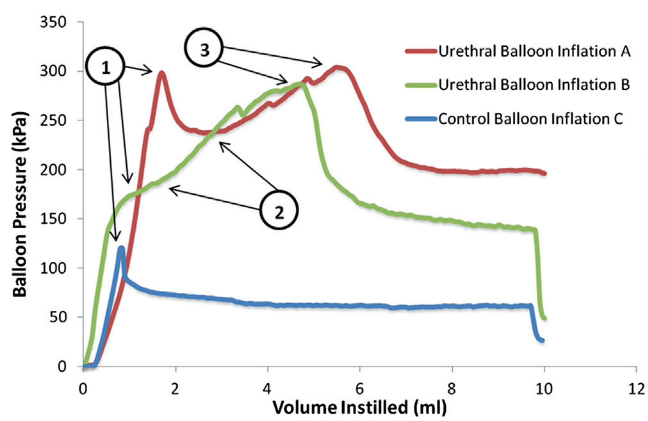

Figure 4. Pressure volume profiles to inflate anchoring balloon in porcine urethras A and B (2 [A + B]) compared to control inflation at atmospheric pressure in urethra C (volume 10 ml). Initially large pressure increase occurred in all 3 samples as balloon distension commenced (*1*). Pressure volume relationships then varied for each sample. In control pressure decreased after initial distension pressure of 120 kPa. In sample A initial 300 kPa peak pressure was required to overcome balloon material properties before pressure decreased. Pressure then decreased to 250 kPa as 2 ml saline were instilled. After this instillation pressure increased as balloon contacted urethral lumen and provided resistance to balloon expansion (*2*). Urethral resistance pressure continued to increase to 300 kPa as continuous inflation to 6 ml occurred. Thereafter inflation pressure decreased acutely, indicating urethral rupture (*3*). In sample B balloon material properties were overcome at 160 kPa (*1*) and rate of pressure change with volume (ie line slope) changed, indicating that balloon had contacted urethral lumen (*2*). Again maximum inflation pressure increased to 280 kPa as continuous instillation occurred. Resistance pressure decreased after 5 ml were instilled, indicating urethral rupture (*3*).

representative of the degree of urethral trauma required to cause rupture (fig. 5).

Internal diametric strain and urethral rupture. The internal diametric strain induced on each urethral specimen due to the inflation process was investigated (fig. 5). Urethral rupture consistently occurred at an internal diametric strain greater than 40% at the 3 and 9 o'clock positions in the bulbar urethra. The maximum pressure recorded in the urethral catheter anchoring balloon during the inflation procedure is also represented. Findings demonstrated no evidence of urethral trauma below an inflation pressure of 150 kPa. The lowest recorded maximum inflation pressure required for urethral rupture was 187 kPa.

Cadaver Testing

Pressure profiles with prototype safety valve syringe. Figure 6 shows pressure profiles during the urethral catheter inflation process in the cadaveric urethra using a prototype safety syringe. Average ± SD maximum threshold inflation pressure before sterile water was decanted through the safety pressure valve was 153 ± 2.99 kPa for physician 1 and 153.91 ± 2.81 kPa for physician 2. There was no statistical difference between the 2 physicians ($p = 0.9$). The mean volume of water infused required to activate the safety valve was 1.35 ± 0.44 ml and 1.29 ± 0.46 ml for physicians 1 and 2, respectively. Again there was no statistical difference between the operators ($p = 0.8$).

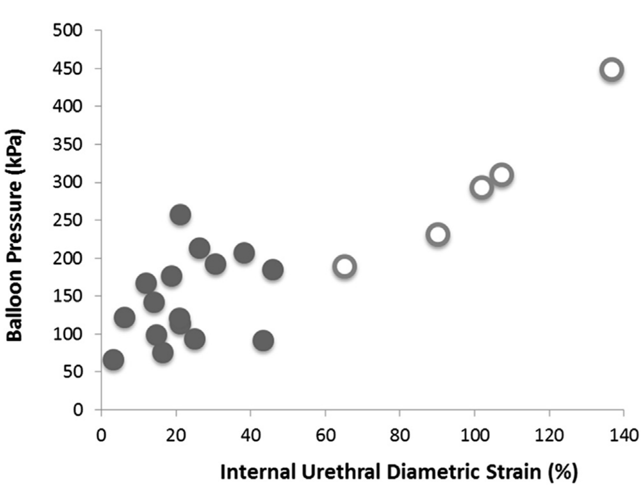

Figure 5. Maximum catheter balloon/urethral pressure and internal diametric strain recorded for each of 21 urethral samples tested. Figure clearly demonstrates safety cutoff of 40% internal urethral diametric strain and/or maximum balloon pressure cutoff of 150 kPa before urethral rupture. Open circles indicate ruptured urethral samples. Filled circles indicate unruptured samples.

Maximum pressure testing with standard syringe. Table 2 shows maximum pressure profiles in the 7 cadaveric urethras using a standard inflation syringe. Mean maximum inflation pressure was 545.09 ± 203.28 kPa for physician 1 and 472.21 ± 260.71 kPa for physician 2. There was no statistical difference between operators ($p = 0.57$). Maximum inflation pressure was significantly greater with the standard syringe compared to the prototype syringe, of which the safety valve was activated at the urethral threshold resistance pressure (mean 504.6 ± 255.74 vs 153 ± 3 kPa, $p < 0.001$). Table 2 also shows a comparative assessment of maximum inflation pressures for a standard syringe in each cadaveric urethra. The average volume of sterile water infused with a standard syringe was 3 ± 0.76 and 2.35 ± 0.38 ml for physicians 1 and 2, respectively ($p = 0.65$). The average volume of sterile water infused was 2.68 ± 0.57 ml with a standard syringe. Activation of the prototype syringe safety valve occurred at a mean of 1.32 ± 0.47 ml, indicating urethral resistance at these volumes. The difference in volume infused in the 2 syringe types was statistically significant ($p = 0.0004$).

Pressure profile at constant flow rate. Figure 7 shows the pressure profile of a catheter balloon inflated in the urethra of a fresh cadaver using a syringe pump at a constant flow rate of 30 ml per minute. Testing was performed with a prototype safety syringe and a standard syringe. Activation of the prototype safety threshold pressure valve occurred at 150 kPa. In contrast, the standard syringe achieved an inflation pressure of 450 kPa before the experimental protocol was discontinued. This pressure difference was statistically significant ($p < 0.001$).

DISCUSSION

A urethral catheter anchoring balloon is inadvertently inflated in the urethra in up to 3% of hospitalized patients with resultant urethral trauma.[5,9] Such iatrogenic complications are associated with considerable costs, financial penalties and longer inpatient stays. Chavez et al reported that the cost of treating urinary tract infections, cystitis and septicemia after traumatic UC was $11,052, $484 and $48,935, respectively, on an annual basis.[10] High incidences of procedural associated complications and their mounting costs highlight a potential opportunity among researchers to design a safety mechanism that eliminates iatrogenic injuries during the UC process. In the current study we investigated strain thresholds for urethral rupture. We found that rupture occurred at an internal urethral diametric strain

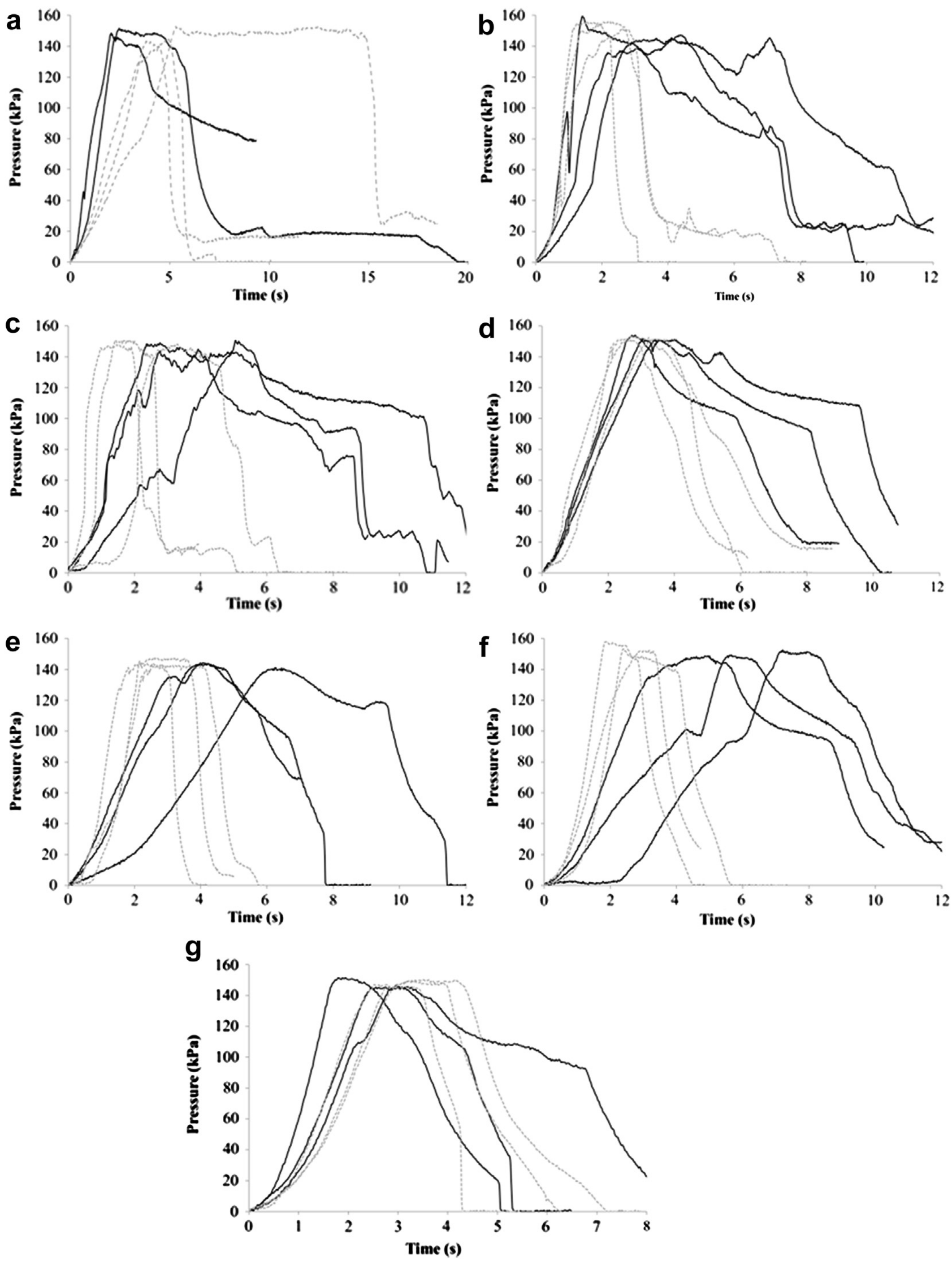

Figure 6. *a* to *g*, pressure profiles during inflation of each catheter in bulbar urethra of 7 cadavers using prototype syringe. There was no significant difference in infused water volume needed to activate safety valve for physician 1 (black curves) vs physician 2 (gray curves) ($p = 0.8$). Maximum inflation pressure achieved was 159 kPa (range 150 to 159). All urethras behaved similarly regardless of operator. As inflation process commenced, there was universal acute or gradual increase in pressure, which was operator dependent. Threshold/maximum inflation pressure was not operator dependent and remained constant for each inflation. After maximum pressure was reached pressure decreased as each operator discontinued inflation.

greater than 40% and/or a maximum inflation pressure greater than 150 kPa in porcine models. Based on these parameters we subsequently designed a safety valve that reliably activated at a threshold pressure of 150 kPa.

The importance of designing a safer transurethral catheter that eliminates the potential for urethral trauma has been recently highlighted.[11] Wu et al emphasized urethral resistance pressure, intravesical pressure and catheter inflation forces

Table 2. *Maximum inflation pressure for standard and prototype syringes in each cadaveric urethra*

	Syringe Max Pressure (kPa)	
Cadaver No.	Standard	Prototype
1	498	151
2	737	159
3	664	150
4	279	153
5	552	152
6	589	152
7	493	151
Mean	545	153

in newtons as important elements that should be investigated to design a transurethral catheter that eradicates the potential for urethral trauma.[11] Those promising data were limited in that the pressure threshold after inflating the balloon in the urethra was not investigated. This particular feature was investigated in the current study. We determined that an excess of 150 kPa may be sufficient to precipitate urethral trauma during the inflation process. We also noted that inflation pressures greater than 700 kPa could be generated during the balloon inflation process with a standard syringe. This finding highlights the potential danger inherent in current catheter design, such that this pressure can be generated but remain unknown by an inexperienced operator. Therefore,

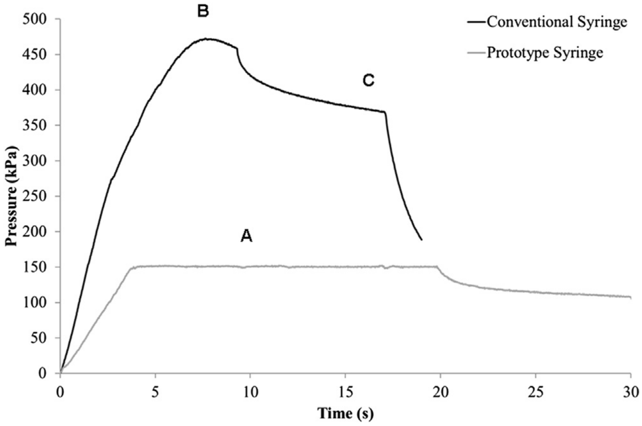

Figure 7. Pressure profiles of catheter inflated in cadaveric urethra using flow resistance technique with syringe pump at infusion rate of 30 ml per minute. Testing was performed with standard (black curve) and prototype (gray curve) syringes. Prototype curve clearly shows safety of novel prototype safety syringe as maximum inflation pressure was limited to safe plateau pressure of 150 kPa up to 20 seconds (*s*), when inflation process was completed (*A*). In contrast, flow resistance approach with standard syringe achieved inflation pressure of 450 kPa (*B*). Inflation pressure decreased at approximately 8 seconds, indicating that urethral threshold pressure was breached. Pressure continued to decrease until inflation was discontinued at approximately 16 seconds (*C*).

designing a safer UC with lower maximal threshold inflation pressures could significantly decrease the potential for iatrogenic urethral trauma during the catheterization process.

A number of important findings are demonstrated by the current study. We initially found that misplaced anchoring balloon inflation will cause urethral rupture when the internal urethral diameter is increased to greater than 40% of its original diameter. Diametric strain measures the change in luminal diameter due to expansion of the anchoring balloon. It is calculated as the change in diameter divided by the original diameter and consequently expressed as a percentage. In addition to this strain threshold, we noted that an anchoring balloon inflation pressure less than 150 kPa reliably prevented urethral rupture as rupture only occurred at pressures exceeding 150 kPa. User variability during the balloon inflation process can be mitigated using a flow resistance inflation technique since regulating the inflation rate eliminates operator variability and permits sufficient time for the safety valve to activate if the anchoring balloon has been misplaced. Finally, we observed the reliability of the safety pressure valve as it activated after a predefined threshold pressure was breached in each cadaver model for both operators and for every brand of catheter assessed.

Porcine samples were initially selected because their urethral biomechanical properties closely resemble those of human urethral tissue.[12,13] It is also arguable that urethral compliance may have been altered due to the freezing process prior to experimentation. However, previous studies from our laboratory have consistently demonstrated that although freezing and thawing processes compromise tissue cellular properties, mechanical properties remain unaffected.[7,8] Another limitation is that fresh cadaveric urethral pressure profiles may not be truly representative of in vivo situations due to the loss of elasticity/stiffening effects of rigor mortis. However, our study demonstrates a significant trend in fold differences between urethral threshold pressures with a prototype syringe and maximum inflation pressures with a standard catheter syringe, which are likely to remain constant in vivo. Currently we are prospectively collecting and freezing human urethral tissue to validate our findings in a representative human model.

CONCLUSIONS

Inadvertent inflation of a urinary catheter anchoring balloon in the urethra is a persistent cause of morbidity in clinical practice. The current study demonstrates that internal urethral diametric strain and threshold maximum inflation pressures are important parameters to design a safer urethral catheter system. In the future a safety device with a predetermined flow rate and lower threshold inflation may prevent urethral trauma despite inadvertent balloon inflation in the urethra.

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