

Optimal filling solution for silicone Foley catheter balloons

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Abstract – We assessed whether saline, sterile water, or air better maintained filling volume and diameter in a veterinary silicone Foley bulb. The bulbs of 45 8-French silicone Foley catheters were inflated: 15 with 5 mL of sterile water (SW bulbs), 15 with 0.9% saline (S bulbs), and 15 with air (A bulbs). The bulbs were submerged in 30 mL of synthetic urine in a 50 mL conical tube in a 38°C water bath. Five catheters from each group were removed on days 3, 5, and 10 to measure bulb volume and diameter. On days 3 and 5, volume and diameter of SW or S bulbs were significantly greater than those of A bulbs, but were not significantly different from one another. At day 10, only 1 S bulb remained intact, 4 of the 5 SW bulbs were intact, the average volume of the SW bulbs was 2.8 mL, and the A bulbs were all deflated. We conclude that sterile water and 0.9% saline are both acceptable for Foley bulb inflation of 5 d or less, but sterile water might be preferred if bulb inflation must be maintained for more than 5 d.

Résumé – **Solution de remplissage optimale pour les ballons cathéter Foley en silicone.** Nous avons évalué si une solution saline, l'eau stérile ou l'air ont mieux préservé le volume de remplissage et le diamètre d'une poire Foley vétérinaire en silicone. Les poires de 45 cathéters Foley en silicone Charrière 8 ont été gonflés : 15 avec 5 mL d'eau stérile (poires SW), 15 avec une solution saline de 0,9 % (poires S) et 15 avec de l'air (poires A). Les poires ont été immergées dans 30 mL d'urine synthétique dans un tube conique de 50 mL dans un bain d'eau à 38 °C. Cinq cathéters provenant de chaque groupe ont été enlevés les jours 3, 5 et 10 afin de mesurer le volume et le diamètre de la poire. Les jours 3 et 5, le volume et le diamètre des poires SW ou S étaient significativement supérieurs à ceux des poires A, mais n'étaient pas significativement différents l'un de l'autre. Au jour 10, seulement 1 poire S est demeurée intacte, 4 des 5 poires SW étaient intactes, le volume moyen des poires SW étaient de 2,8 mL et les poires A étaient toutes dégonflées. Nous avons conclu que l'eau stérile et la solution saline 0,9 % sont toutes deux acceptables pour le gonflement des poires Foley pendant 5 jours ou moins, mais que l'eau stérile pourrait être privilégiée si le gonflement de la poire doit être maintenu pendant plus de 5 jours.

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Introduction

The Foley catheter is commonly used in veterinary medicine for monitoring patients with urinary tract disease. Specifically, Foley catheters are used to assess urinary output or divert urine in cases of urethral obstruction (1–3). Foley catheters are flexible indwelling catheters that are placed in

patients requiring periods of urethral catheterization. Most Foley catheters are made of silicone, latex, or a combination, and are available in a variety of sizes. Once placed, the balloon is distended with a solution; the inflated balloon then aids retention of the catheter in the urinary bladder.

Premature deflation or malfunction of the Foley catheter bulb confounds patient monitoring. For example, inadequate occlusion at the trigone of the bladder may allow urine leakage around the catheter, giving a falsely low impression of the patient's urine production into a collection cistern. This can result in altered fluid rates, below or above the patient's actual requirements, which can lead to dehydration or fluid overload (4).

Products for use in humans have been studied, but no Foley catheter designed for veterinary use has been evaluated. Previous studies evaluated the type of fluid used to inflate the bulbs of Foley catheters. In 1983, silicone Foley catheters manufactured by Dover and Travenol (commonly used in human medicine), were used to determine which type of filling solution should be used to inflate the bulb (5). In that study, silicone bulbs

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submerged in urine, with sterile water as an inflation fluid, had a marked amount of fluid loss compared with bulbs filled with 0.9% sodium chloride (NaCl) solution. A study in 2004 evaluated Foley catheters made of latex; the results showed no difference in the rate of deflation when filling the bulbs with sterile water or a 0.9% NaCl solution (6).

There is controversy within the veterinary community concerning the appropriate filling solutions. The manufacturer of the Foley catheters used in the present study recommends sterile water as the appropriate instilling solution; however, there are published veterinary protocols recommending sterile saline as a filling solution (4,7). This underscores the importance of our investigation wherein we attempt to determine an appropriate inflation medium for a Foley catheter specifically marketed to veterinarians in a size that is commonly used in veterinary hospitals (8 French) (4).

Our objective was to compare air, sterile water, and saline for short-term inflation of a veterinary silicone Foley catheter bulb. Saline and sterile water were selected based upon anecdotal experience indicating that both appear to maintain placement of a Foley catheter in veterinary patients. Air was selected as a control because deflation was expected. We hypothesized that sterile water and a 0.9% NaCl solution would maintain greater Foley bulb diameter and inflation volume than air at days 3, 5, and 10. Further, we hypothesized that there would be no significant difference in bulb diameter and inflation volume between sterile water and a 0.9% NaCl solution.

Materials and methods

A total of 45 8-French 55 cm long veterinary Foley silicone catheters (8 French urinary Foley catheter; Smith-Medical PM, Veterinary Division, Waukesha, Wisconsin, USA) were used. Fifteen bulbs were inflated with the manufacturer's recommended volume of 5 mL of sterile water (SW bulbs), 15 bulbs were inflated with 5 mL of 0.9% NaCl solution (S bulbs), and 15 bulbs were inflated with 5 mL of air (A bulbs, control group). Prior to filling the Foley bulbs, each catheter's bulb was test inflated with 5 mL of air to ensure integrity of the bulb and inflation valve. On the day of inflation, the total volume of the inflation solution was recorded and a measurement was obtained of each bulb's largest diameter. Using a caliper, the widest point was identified by eye and each bulb's maximal circumference was measured and recorded. Upon completion of the initial data collection, each catheter's bulb was completely submerged into a synthetic urine bath at 38°C (Sarine; Dyna-Tek Industries, Lenexa, Kansas, USA). Three drops of sodium azide were added to the synthetic urine to prevent growth of bacteria. The osmolarity of the synthetic urine was measured with a microosmometer.

The warm synthetic urine baths were prepared as follows. Each of the 45 50-mL conical centrifuge tubes (BD Biosciences, Franklin Lakes, New Jersey, USA) contained 30 mL of synthetic urine and 1 completely submerged 8 French Foley catheter bulb. A small hole was drilled into the lid of each centrifuge tube, 1 Foley catheter was inserted into each hole, and the bulbs were inflated with 5 mL of air, sterile water, or sterile 0.9% NaCl solution. Each centrifuge tube was then filled with 30 mL of

Table 1. Mean volume of liquid or air in the bulbs of Foley catheters on days 0, 3, 5, and 10

Medium	Foley bulb volume (mL ± s)			
	Day 0	Day 3	Day 5	Day 10
Air	5 ± 0	0 ± 0	0 ± 0	0 ± 0
Sterile water	5 ± 0	3.20 ^a ± 1.788	2.84 ^a ± 1.589	2.24 ^a ± 1.252
Saline	5 ± 0	3.16 ^a ± 1.768	3.8 ± 0	1.07 ^b ± 7.505

s — standard deviation.

^a Ruptured bulbs were included in the calculation as 0 with the exception of the saline group at day 10.

^b This mean was calculated using 3 Foley catheters because 2 ruptured at day 0. However 2 of the remaining 3 bulbs that were found to be ruptured at day 10 were included in the calculation as 0 when calculating the mean.

synthetic urine to allow for complete submersion of the catheter bulb. A piece of tape was placed on the lid covering the hole and catheter allowing for catheter identification, assurance of complete submersion of the bulb, and prevention of evaporation of the synthetic urine. Each centrifuge tube was submerged in a water bath to the height of the synthetic urine. A thermometer was placed in the water bath to monitor the maintenance of the 38°C temperature.

On day 3, 5 SW bulbs, 5 S bulbs, and 5 A bulbs were removed from the synthetic urine bath. Diameter and volume measurements were recorded for each bulb and the catheters were discarded. This procedure was repeated on days 5 and 10.

Statistical methods

Two-way repeated measures analysis of variance [factors: time (baseline, 3 d, 5 d, 10 d) versus inflation substance (sterile saline, sterile water, air)] was applied to determine if there was a difference among the inflation materials over time. When a significant difference ($P < 0.05$) was detected, the Holm-Sidak post hoc test was applied.

Results

The measured osmolarity of the synthetic urine was 706 mOs/kg. Of the 45 catheters, 2 Foley bulbs of the S group ruptured at day 0 at the time of submergence into the synthetic urine. Therefore, the remaining 43 catheters were allocated into 3 groups: air ($n = 15$), sterile water ($n = 15$), and 0.9% saline ($n = 13$). The mean volumes of air, water, and saline on days 0, 3, 10 (Table 1) and the mean diameters (Table 2) were recorded.

On day 3, S and SW bulbs had a significantly greater volume ($P = 0.006$) and diameter ($P = 0.021$) than A bulbs, but there was no significant difference in volume or diameter between S and SW bulbs. On day 3, comparison to baseline revealed a significant difference in volume ($P < 0.001$) and no significant difference in diameter ($P = 0.875$) for SW bulbs. On day 3 there were no significant differences in volume ($P = 0.125$) or diameter ($P = 0.875$) of S bulbs compared to the baseline. There was 1 ruptured Foley bulb in each of the SW and S groups. The A bulbs ($n = 5$) were all deflated on day 3, but were still intact. Only the A group had a significant decrease in volume ($P < 0.001$) and diameter ($P < 0.001$) on day 3 compared to day 0.

On day 5, S and SW bulbs had a significantly greater volume ($P < 0.001$) and diameter ($P < 0.001$) than A bulbs, but no

Table 2. Mean diameters of the Foley bulbs for each group on days 0, 3, 5, and 10

Medium	Foley bulb diameter (mm \pm <i>s</i>)			
	Day 0	Day 3	Day 5	Day 10
Air	13 \pm 0	0 \pm 0	0 \pm 0	0 \pm 0
Sterile water	15.66 \pm .320	12.44 ^a \pm .541	12.2 ^a \pm 6.823	10.06 ^a \pm 5.693
Saline	15.5 \pm .452	12.78 ^a \pm 7.144	15.32 \pm .342	4.33 ^b \pm 7.505

s — standard deviation.

^a Ruptured bulbs were included in the calculation as 0 with the exception of the saline group at day 10.

^b This mean was calculated using 3 Foley catheters because 2 ruptured at day 0. However, 2 of the remaining 3 bulbs that were found to be ruptured at day 10 were included in the calculation as 0 when calculating the mean.

significant difference was noted in volume or diameter between the S and SW groups. On day 5, the SW bulbs had a significant difference in volume ($P < 0.001$) and no significant difference in diameter ($P = 0.188$) compared to day 0. Within the S group there was no significant difference in volume ($P = 0.063$) or diameter ($P = 0.291$) on day 5 when compared to the baseline. There was only 1 ruptured catheter bulb and it was identified in the SW group. The A group catheter bulbs ($n = 5$) were all deflated but intact. Once again, the A group bulbs on day 5 compared to day 0 had a significant decrease in volume ($P < 0.001$) and diameter ($P < 0.001$).

Comparisons could not be made between the 3 groups on day 10, due to the large number of ruptured bulbs within the S group. However, the S and SW bulbs had noticeably greater volumes and diameters than A bulbs. Only 1 of the S bulbs was still intact, whereas 4 of the 5 SW bulbs were intact. The volume of the single intact S Foley bulb was 3.2 mL while the average volume of the SW bulbs was 2.8 mL. On day 10 SW bulbs were significantly different in volume ($P < 0.001$) but not in diameter ($P = 0.108$), compared to baseline values. The S group bulbs had no significant difference in volume ($P = 0.066$) or diameter ($P = 0.125$) on day 10 when compared to baseline.

Discussion

Measurement days were selected based on clinical experience and previous studies. One study recommended catheter removal at day 3 due to increased susceptibility to urinary tract infection after 3 d (8). However patient conditions sometimes dictate use of a Foley catheter for extended periods. Examples include urethral pathology or treatment of renal insufficiency where the clinician is awaiting stabilization of the patient. Another reason for prolonged catheterization is assisting in nursing care for paralyzed patients or patients suffering from spinal trauma. These diseases may require catheterization up to 10 d and beyond. In fact, 1 study evaluated Foley bulbs instilled with fluid for up to 4 wk (6).

The most conclusive finding of the present study is that air is unacceptable when used for inflation of Foley catheter bulbs. Air was chosen as the control because deflation was expected. The deflation may be linked to the composition of the catheter bulb, as the silicone material of the Foley bulb is semi-permeable, allowing easy diffusion of air across the bulb. When using saline or sterile water as instilling solutions, a previous study noted the diffusion potential of a silicone catheter bulb and concluded that diffusion does occur, but may not be solely responsible for deflation of the bulb (5). Another explanation for the uniform

deflation of the air-filled Foley bulbs is that the inlet valve of the bulb may allow small amounts of air and/or water to leak through the seal, leading to deflation. While our study did not include any additional interventions to augment this inlet valve seal, a previous study used a silk suture that was tied behind the inlet valve (5). A significant amount of the instilled fluid was still lost, indicating that the decrease in bulb fluid was not due to leakage through the inlet valve (5).

Despite the presumed lack of leakage through the inlet valve, loss of fluid solutions from the Foley bulb occurred in our study. While diffusion across the semi-permeable membrane of the bulb is a rational explanation for loss of air, it is unclear if diffusion loss occurs with 0.9% saline and sterile water. Osmotic force is determined by the number of particles in a solution (9). A fluid with a lesser particle concentration will move across a semi-permeable membrane to an area of a greater particle concentration (9). The normal urine osmolarity range is 50 to 2700 mOsm/kg in dogs and 50 to 3200 mOsm/kg in cats (10). The osmolarity of the synthetic urine used in the present study, 706 mOsm/kg, was in the normal range of dog and cat urine. Sterile water has an osmolarity of zero; therefore, when sterile water is used as a filling solution for a semi-permeable Foley catheter bulb placed in a urine-like substance, the osmotic force will be greater towards the urine-like substance, causing movement of water out of the bulb and resulting in a reduction of the Foley bulb diameter (5). Similarly, the sterile 0.9% NaCl solution used herein has a calculated osmolarity of 308 mOsmol/L; therefore, osmotic force towards the urine-like substance will be present but should be less than that of water. Saline-filled bulbs are therefore expected to deflate less than water-filled bulbs. However, in this study, there was no apparent diffusion difference between water and sodium chloride until day 10.

The use of synthetic urine in this study allowed for complete predictability in regards to the urine. If pooled urine of canine or feline patients were used, additional variables would have been introduced into the study such as the presence of glucose, proteins, or abnormal urine concentration. It was important to establish an appropriate filling solution in essentially "normal" urine. If large amounts of glucose, proteins, or abnormal urine concentration were present, the osmolarity and content of the urine may have been affected. In turn, this might be expected to affect movement of the instilled material. Future studies could use animal urine that is iso-or-hyposthenuric or that contains excessive amounts of glucose or proteins.

An additional concern, discussed in a 2004 study, is the potential complication of crystal formation with the use of NaCl

solution as an instilling solution (6). Crystal formation in the Foley bulb could prevent full deflation and, therefore, inhibit removal of the catheter. As in the 2004 study, crystal formation in the Foley bulb did not occur in the present study. However, our study may not have allowed enough time for crystal formation to occur. Microscopic evaluation of the fluid for crystal formation in the 0.9% saline bulbs may be warranted for future studies to definitively rule out crystal formation.

The rupture of all but 1 saline-filled bulb at day 10 could be explained by an osmotic pull of synthetic urine into the bulb, expanding the bulb and leading to rupture. However, the osmolarity of the NaCl solution was less than that of the synthetic urine. It is possible that the osmolarity of the synthetic urine could have changed over time so that by day 10 it was less than that of the saline solution. A future study could incorporate daily osmolarity measurements of the synthetic urine and/or add dye to the instilling solution to determine if osmotic movement across the barrier occurs and to better chart the fluid fluxes within the Foley bulbs. These 2 interventions may provide a clear reason for the rupture of the bulbs. Nevertheless, if diffusion into the Foley bulb led to bulb rupture, one would expect the volume of the saline-filled bulb to be greater at day 10 as fluid from its environment filled it. We do not know the reason for this result in our study. A future study design could also incorporate daily evaluation of the Foley bulbs' volume and diameter to determine subtle incremental changes over time. Knowing more precisely the times when the bulbs burst and daily changes in bulb diameter leading up to the ruptures could shed light on the cause of the ruptures.

The most surprising finding was the total number of catheter bulb ruptures regardless of filling solution. Approximately 17% of catheter bulbs ruptured despite each catheter bulb being filled with the recommended volume. According to a company representative (Don Shawver, Smith Medical PM, Veterinary Division, Waukesha, Wisconsin, USA, personal communication, 2006), Foley bulbs can rupture with minor over-inflation, although larger capacity bulbs (on 8 French and 10 French catheters) do not rupture as readily as smaller capacity bulbs when filled with the recommended amount of inflation solution. It is recommended, therefore, that the bulb be inflated slowly and with the recommended volume to reduce the chance of bulb rupture. We do not have a convincing explanation for the rupture of the 8 French Foley catheter bulbs in this study since they were filled with the volume directed and at a slow rate. One theory is that the integrity of the bulbs may have been compromised by the test inflation or a residual amount of test air could have remained in the bulb, resulting in over inflation once the solution or additional air was instilled. Future studies could include a group with test inflated catheters and another group without.

The high and unexpected rupture rate may help to dictate a proper filling solution. If bulb ruptures occur in patients, the medium released into the bladder from the Foley bulb could play a role in the overall health of the patient. Non-sterile solutions could increase the risk of urinary tract infections and air

within the urinary bladder can result in an air embolism within the vasculature. Air embolism is thought to occur in patients with an actively hemorrhaging bladder mucosa (11). Air is thought to gain access through the venous system via bleeding capillaries, leading to fatality (12). The potential risk of an air bubble being released from a Foley bulb inflated with air and leading to a potential deadly result warrants further consideration. The release of sterile water or saline does not carry any potentially deadly complications.

Based on the results of this *ex vivo* synthetic urine model, sterile water and 0.9% saline should both be acceptable for Foley bulb inflation of ≤ 5 d, but sterile water might be preferred if Foley bulb inflation must be maintained for > 5 d. However, it is difficult to make a strong conclusion on the difference at day 10 between saline and water-filled bulbs, because there was only one remaining saline-filled bulb available for comparison.

Further investigation is necessary to see if similar results are obtained *in vivo*, although we are confident in concluding that air is not acceptable for Foley bulb inflation. Future studies with larger numbers of catheters are also indicated to more closely evaluate bulb rupture rate.

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