Research Article

The burst catheter balloon: A comparison of fragmentation rates and overinflation burst volumes in Foley catheters with special considerations in SCI

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Objective: The primary aim was to determine Foley catheter balloon burst volumes and the effect of latex Foley catheter size on balloon burst volume. The secondary aim was to measure the effect of Foley catheter material on free fragment formation rate. This study also focused on special considerations for those with neurogenic bladder and spinal cord injury at or above T6.

Methods: This study analyzed 83 various sized silicone (n = 14) and latex (n = 69) Foley catheters. All catheters had 5 mL balloons. Each catheter was overinflated in vitro with water until the balloon ruptured, with volume (mL) and fragment formation recorded upon rupture. The effect of catheter size on the number of free fragments and burst volume was measured with linear regression. The likelihood of free fragment formation was compared between silicone and latex catheters with significance measured using Fisher's Exact Test.

Results: Free fragment formation occurred in 90% (62/69) of the latex catheters compared to 0% (0/14) of the silicone catheters. A higher proportion of free fragment formation occurred in latex catheters when compared to silicone catheters ($P < 0.001$). There was a positive effect of catheter size on burst volume ($P < 0.001$).

Conclusion: Balloon rupture by overdistention is an effective way to remove a retained catheter due to a non-deflating balloon. Post-bursting free fragment formation is common in latex balloons. This highlights the need for cystoscopy. Additionally, due to large fluid volumes needed to burst the balloon, this method should be discouraged in those at risk for autonomic dysreflexia.

Keywords: Balloon fragment, Overinflation, Non-deflating catheter, Autonomic dysreflexia, Spinal cord injury

Introduction

Neurogenic bladder commonly results from spinal cord injury (SCI). There are a number of reasons that individuals with SCI may have their bladder managed by indwelling urethral and suprapubic catheters.[1] During attempts at catheter removal, healthcare providers working with individuals with SCI may encounter a situation in which an inflated catheter balloon will not deflate with active aspiration of the inflation channel using a syringe. Instilling 1–2 mL of fluid through the balloon port valve will sometimes "unblock" the balloon port and allow drainage. Alternatively, making sure the aspiration syringe is fully engaged, depressing the balloon port valve, and allowing for passive aspiration through prolonged attachment of the syringe to the balloon port will sometimes drain the balloon.[2] Cutting the catheter's side arm proximal to a potentially faulty valve has also been described.[2] However, if unsuccessful at draining the balloon, it will then be extremely difficult to instill fluid through the residual side arm in order to burst the balloon using overinflation.

In cases where aspiration is not successful, non-invasive techniques may be attempted such as rupture of the balloon by overinflation or guide wire/stylet insertion

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into the inflation channel to either regain patency or pierce the balloon.[2–6] While easy to perform, the overinflation technique may not be the best technique in those who have a non-deflating 30 mL catheter balloon rather than the standard 5 mL balloon. This is because with the 30 mL balloon a much larger amount of fluid would have to be instilled into the balloon in order for the balloon to burst, which may cause bladder discomfort or pain prior to balloon bursting. It would also be much more likely to cause autonomic dysreflexia (AD) in those with SCI at thoracic level 6 (T6) and above. An additional non-invasive method of balloon rupture with chemical instillation has been previously described but is generally not recommended given potential complications including bladder pain and irritation.[2,3,5,7–9]

More invasive methods for catheter removal with balloon rupture have evolved over time; these include ultrasound-guided suprapubic needle puncture, transurethral puncture, and transvaginal puncture.[2–5] Many of these recommended methods, particularly invasive techniques, require urology consultation and tools that may not be readily available in all healthcare institutions. Moreover, non-invasive techniques may have an advantage over invasive techniques in that in addition to being non-invasive, they do not require special equipment and expertise.

A concern of all catheterization methods that employ balloons is the possibility of retained balloon fragments in cases of ruptured balloons.[10,11] In 2015 Mishra[11] reported a case in which a female who, one year after a hospitalization complicated by a non-deflating urethral catheter, presented with retained balloon fragments in the bladder. Retained balloon fragments may act as niduses for stone formation if not detected and removed.[10–14] This is especially relevant in patients with SCI who may already be at higher risk for bladder stones due to bacterial colonization and related complications, including recurrent urinary tract infections (UTI), hematuria, and AD.[13.]

There is limited literature describing urethral catheter balloon fragmentation patterns and burst volumes. It has been reported that 12–15 times the balloon's normal capacity is required when hyperinflating a catheter balloon to the point of rupture.[8] Eickenberg *et al.*[4] described Foley catheters ranging in size from 18–24 French (Fr) that had been used by patients for 1–6 weeks and were then overinflated in vitro with water; these balloons demonstrated burst volumes of 100–170 mL. Gulmez *et al.*[15] investigated 18Fr silkolatex Foley catheters with recommended balloon inflation volumes of 30–50 mL; this study found that after 48hr inflated with the recommended 30 mL and immersed in urine, an additional 78–217 mL caused the balloons to burst, with an 83% free fragment formation rate.

In cases where balloon rupture is used in order to deflate the balloon, cystoscopy is generally considered to be the gold standard used to evaluate for and remove balloon fragments in the bladder. Since cystoscopy is invasive, further research in this area is needed to explore patterns of free fragment formation and potentially high-risk burst volumes in Foley catheters. More cohesive data may corroborate the recommendation against overinflation and highlight the need for routine cystoscopy in patients with indwelling urethral catheters.

This study was exploratory with the overall intent of observing patterns of fragmentation in Foley catheters burst by overinflation, which has important clinical implications. The primary aim of the study was to determine the effect of Foley catheter size and material on free fragment formation rate of catheter balloons when overinflated to the point of rupture. Free fragment formation rate refers to a measure of frequency in this study. The secondary aim was to identify the effect of latex Foley catheter size on catheter balloon burst volume when overinflated to the point of rupture. The third aim was to discuss considerations which should be taken into account when performing this procedure in those at risk for AD.

Methods

This study analyzed the burst volume and fragmentation patterns of various sizes of latex and silicone Foley catheters in vitro. This study did not involve human subjects. A convenience sample of both non-expired and expired catheters from a single manufacturer was tested, and all catheters were new and unused. Expired latex catheters were all within 6 months of expiration. Silicone catheters with unmarked expiration date labels were conservatively counted as 'expired.' All catheters had 5 mL horizontal ribbed balloons with recommended inflation volumes of 10 mL.

The balloon end of each catheter was placed in a plastic bottle to contain any fragments upon bursting and was overinflated with tap-water using a 30 mL syringe with brief pauses between inflation to refill the syringe. Balloons were overinflated until they burst, with volume (mL) recorded at the time of rupture. The number of free balloon fragments was recorded for each ruptured balloon. Data were transcribed to a computer database. All statistical analyses were performed using Microsoft Excel, with $P < 0.05$ considered statistically significant.

Table 1 Foley Catheter Sample.

Material	Tube Size (Fr)	n	Expired	Non-expired
Silicone	12	9	9	0
Silicone	18	5	0	5
Latex	12	19	19	0
Latex	14	3	0	3
Latex	18	5	0	5
Latex	20	8	8	0
Latex	22	15	10	5
Latex	26	3	0	3
Latex	28	16	10	6

Mean burst volumes and the mean number of fragments were calculated. The likelihood of free fragment formation was compared between the silicone and latex catheters with statistical significance measured using Fisher's Exact Test. The effect of catheter size on the number of formed free fragments and on the burst volume in the latex catheters was measured with linear regression tests. Using linear regression tests, these effects were again measured with the latex catheters stratified into expired and non-expired groups.

Results

The study analyzed 83 silicone (n = 14) and latex (n = 69) Foley catheters (Table 1). Of the total sample, 33% were non-expired and 67% were expired. Silicone catheters with the following sizes were included: 12Fr (n = 9) and 18Fr (n = 5). Latex catheters with the following sizes were included: 12Fr (n = 19), 14Fr (n = 3), 18Fr (n = 5), 20Fr (n = 8), 22Fr (n = 15), 26Fr (n = 3) and 28Fr (n = 16).

At least one free fragment was formed in 90% (62/69) of the latex catheters compared to 0% (0/14) of the silicone catheters (Figure 1). Free fragments per burst catheter ranged from 0 to 4 pieces, with fragment size ranging from 1mm^2 to 630mm^2. There was a significantly higher proportion of free fragment formation in the latex catheters when compared to the silicone catheters ($P < 0.001$).

The average burst volumes for each latex catheter size were: 66 mL for 12Fr, 93 mL for 14Fr, 115 mL for 18Fr, 123 mL for 20Fr, 168 mL for 22Fr, 245 mL for 26Fr, and 227 mL for 28Fr. There was a highly significant positive effect of catheter size on burst volume (Figure 2) ($P < 0.001$). The observed effect of catheter size on burst volume was still present when the latex catheters were stratified into expired ($P < 0.001$) and non-expired ($P < 0.001$) groups. No significant effect of catheter size on the number of formed free fragments was found; this was unchanged when the catheters were stratified into expired and non-expired groups.

Discussion

The overall fragmentation rate in the latex catheters (90%) in this study is well-aligned with a previously reported fragmentation rate of 83% in overinflated latex catheters.[15] The high rate of free fragment formation in the latex balloons suggests that it is especially important to perform cystoscopy and inspect for retained balloon fragments in cases where latex catheter balloons either incidentally burst or were intentionally burst in order to remove the catheter. In our own experience, a patient incidentally may be found to have intrabladder catheter balloon fragments (Figure 3). This is another reason, in addition to possible stones, tumors, and foreign bodies like pubic hairs, that we recommend routine annual cystoscopy.

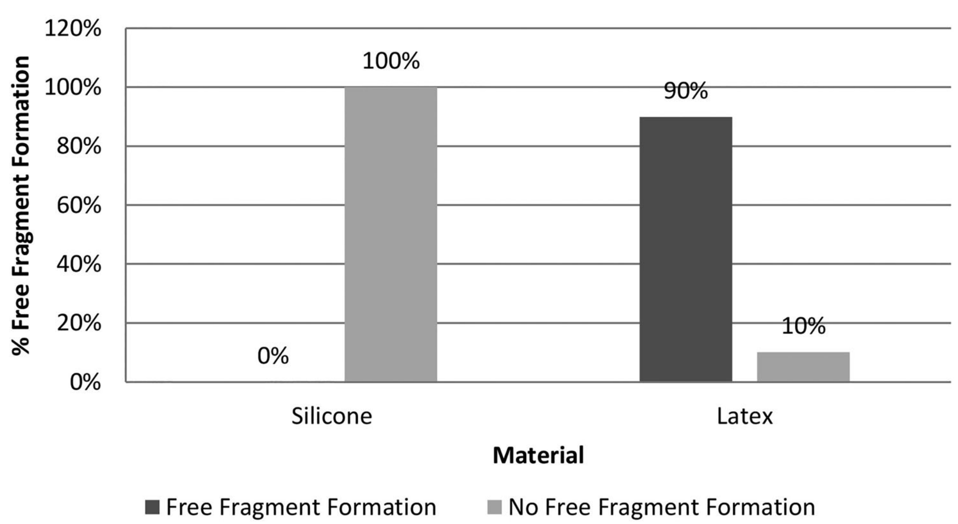

Figure 1 Foley Catheter Free Fragment Formation.

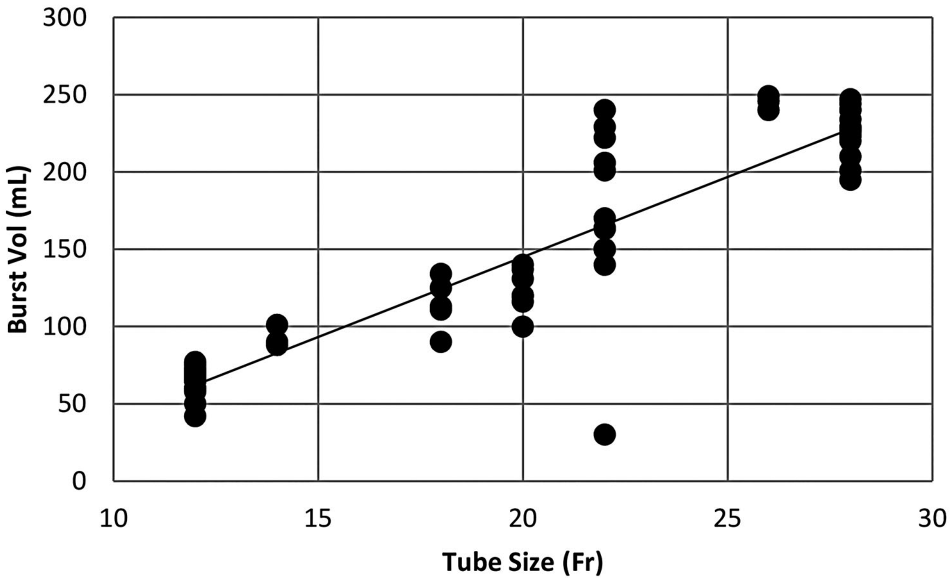

Figure 2 Latex Foley Catheter Balloon Burst Volume.

There was a significant difference in fragment formation between the latex and silicone catheters, with no free fragments observed in the burst silicone balloons. This finding supports that fragmentation rates in catheters differ by material, and certain materials therefore pose higher risks for retained fragments. However, in a study by Chrisp *et al*.[16] similar fragmentation rates were found between teflon-coated latex catheters and silicone catheters when burst by needle puncture (29.3% and 25.3%, respectively). This suggests that fragmentation rates between catheters of different materials may also vary depending on the bursting method.

Despite the same 5 mL balloon size, catheters with larger Fr sizes required larger volumes of instilled water and thus higher internal pressures to burst their balloons. While a high risk for retained fragments is a frequently cited reason to discourage the overinflation technique, the large burst volumes observed in this study lend an additional angle towards advising against this technique. With such large volumes required for rupture, AD becomes an important consideration in patients who are prone to AD. Neurogenic bladder may lead to decreased bladder volume, decreased bladder compliance, and bladder overactivity predisposing these individuals to AD. Overdistension of the catheter balloon and catheter manipulation is likely to provoke AD. In such individuals invasive techniques or overinflation should be used in a setting where blood pressure can be carefully monitored and treatment for AD is immediately available such as an SCI clinic, emergency room, operating room, or same day surgery center since further distending a balloon may cause or exacerbate AD. Additionally, these techniques should be done with a team well-experienced in evaluating and managing AD. A recently developed Paralyzed Veterans SCI Consortium clinical practice guideline titled "Autonomic Dysreflexia and related Autonomic Dysfunctions" is an excellent resource for evaluation and management of AD.[1]

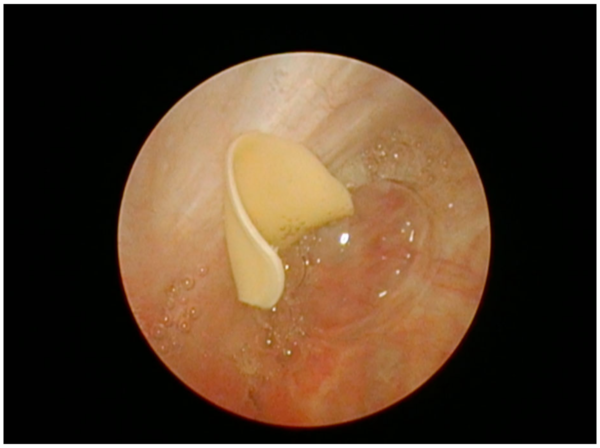

Figure 3 Free Balloon Fragment Identified on Cystoscopy.

In addition to AD, individuals with SCI and indwelling catheters are at risk for UTI; there are special periprocedural considerations for this population. Due to the likelihood of bladder colonization and that increased manipulation of the catheter and balloon may "stir up" the person's microbiome causing a UTI, empiric antibiotics should be considered. A urine culture and sensitivity should be obtained prior to administering the empiric antibiotic in case a person develops a post-procedure UTI and culture-specific antibiotics are needed.

Cystoscopy, while invasive, has been proven to be the gold standard for evaluation and removal of balloon fragments. In a 2006 review by Patterson *et al.*[9] on management of the non-deflating catheter, it was suggested that following removal methods involving balloon puncture, the balloon should be inspected for missing fragments so that cystoscopy may be performed in any case where free fragment formation is suspected. Similar to this study, prior studies have also reported wide ranges of free fragment sizes.[15,16] After identifying free fragments as small as $4mm^2$, Chrisp *et al.*[16] recommended cystoscopic evaluation for any case of a ruptured balloon, suggesting that visual inspection alone may not be adequate. Our results are in agreement with this recommendation for latex catheters but not pure silicone catheters.

There were several limitations to this study. A proportion of the tested catheters were expired, though the same results were obtained following statistical analysis performed on each subgroup. Additionally, the overinflation technique historically involves prefilling the bladder with fluid; the balloons in this study were burst in empty plastic bottles and were not submerged in fluid prior to overinflation. Clinically, a catheter balloon would potentially be sitting inflated in the bladder for 2–4 weeks; these conditions were not mimicked by this study, which may or may not have impacted the results. Moreover, this study was performed in vitro, so the risks of AD in those with SCI at T6 or above with in vivo catheter balloon overinflation are presumed.

Future research in the area may include studies to validate this study's findings in a sample of catheter balloons that have been both inflated for some period of time, as well as submerged in fluid prior to overinflation to better reflect physiologic conditions. This study found differences in fragmentation rate depending on catheter material that were not observed in similar prior studies of punctured catheter balloons; additional research to resolve these conflicting findings may be beneficial. In 2010 a recommendation was made by Singh *et al.*[14] to periodically deflate and re-inflate the balloon of any indwelling catheter used for over 3 weeks in order to break up possible encrustation; for this reason, it may also be useful to measure the effect of balloon deflation and re-inflation on burst volumes and fragmentation patterns. While not a limitation, it should be emphasized that this study only evaluated latex and pure silicone catheters. There are a number of other catheter compositions such as silicone coated catheters.

There may be instances in which balloon overinflation is used for catheter removal. Conversely, an indwelling catheter balloon being removed may be discovered to have already ruptured. In the case of an individual with SCI prone to AD, special considerations must be taken including BP monitoring during balloon rupture and cystoscopic removal, as well as ruling out retained balloon fragments that may provoke stone formation, particularly since the individual might not be able to void.

In summary, we tested balloon rupture of catheters made of two different compositions, latex and pure silicone. This study emphasizes the importance of a cystoscopic evaluation particularly in any case involving a ruptured latex Foley catheter balloon. Special considerations are needed in those with neurogenic bladders, especially individuals with SCI who are prone to AD.

Data availability statement

The data that support the findings of this study are available from the corresponding author, CG, upon reasonable request.

Disclaimer statements

Contributors None

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Disclosure statement Authors have no conflicts of interest to declare.

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