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Pilot Study

A Pilot Study of Foley Catheter Balloon Volumes and Pullout Forces in Females Cadavers

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Abstract

Objective

To evaluate the pull-out force needed to dislodge Foley catheters with various volumes of fluid.

Methods and Materials

Data points were measured by randomizing 7 unembalmed female cadavers. Foley catheters were filled with either 5 mL or 10 mL of water. The force needed to pull-out the catheter was measured using a force gauge.

Results

The mean force required to remove a catheter with the balloon filled with 5 mL of water was 1.24 kg whereas the mean force required to remove a catheter with 10 mL was 3.82 kg. The secondary phase of the study investigated force required to remove a catheter with the balloon filled with 10 mL after a 5 mL filled balloon had previously been pulled out and this was 2.54 kg (33% reduction).

Conclusion

Foley catheter balloon fill volumes have been standardized without clear data indicating the basis for recommendations. This study provides the first normative data about the pull-out pressures needed to dislodge an indwelling Foley catheter in women.

Keywords: Bladder; Catheter; CAUTI; Foley; Pullout

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Introduction

Indwelling Foley catheters are used around the world in every healthcare setting as a means for draining the bladder. Simplified, the Foley catheter is a flexible, hollow tube with an inflatable balloon on the indwelling end that functions to keep the catheter from falling out after it has been placed into the bladder. Despite the ubiquity of this device, the scientifically derived data regarding its use is limited. As one example, manufacturer guidelines for use of a 16 Fr Foley catheter with a 5 mL balloon recommends filling the balloon with 10 mL of sterile water [1]. The 10 mL inflation volume has become an almost universal standard though it is unclear on how this recommendation was derived. A search of the literature revealed only one study investigating balloon fill volumes and pull out forces [2]. This study was performed with three male cadavers. While these data may seem trivial, unnecessarily high catheter balloon volumes may influence catheter-associated patient discomfort, leakage around catheter, catheters related trauma to bladder mucosa or urethra, and possibly Catheter-Associated Urinary Tract Infections (CAUTI's).

While the most effective method of reducing Foley catheter related complications is by avoiding unnecessary placement, this cannot always be prevented. Infection is a well-known and well-studied complication of indwelling Foley catheters [3]. Leuck et al., reveals that genitourinary trauma may be just as common as CAUTI occurrence. Genitourinary trauma related to catheter use occurred in 1.5% of indwelling urethral catheter days. Reducing the occurrence of trauma would, also, likely reduce hospital stay and chance for infection [4]. Currently, there is no literature investigating the correlation between balloon fill volumes, pull out forces, and genitourinary trauma. It is apparent that further studies must be done to help understand why non-infectious complications arise and how to reduce their occurrence. The pilot study described here was designed to determine the force needed to remove an inflated catheter balloon from female bladders with the goal of providing normative data for potential future research.

Materials and Methods

Seven 16 Fr silicone Foley catheters (CR Bard, Inc., Murray Hill, NJ) were placed into the bladders of seven randomly assigned fresh, unembalmed female cadavers in a standard fashion. Of note, all cadavers were obtained directly by the University of Louisville School of Medicine with the intention of medical training and research. This study is IRB exempt since the subjects are deceased and previously donated their bodies to science. For this same reason, informed consent was not needed. The *ex-vivo* placed catheters were then randomly assigned to be filled with either 5 mL or 10 mL of water. The approximate measured dimensions of the 5 mL distended balloon were: Height 17 mm, diameter 22 mm. The approximate measured dimensions of the 10 mL distended balloon were: Height 25 mm, diameter 27 mm. The catheters were than forcibly removed and the maximum force was recorded using a force gauge (Force One FDIX, Wagner Instruments, and Greenwich, CT). After the force measurements were obtained from the cadavers with catheters filled with 5 mL, second catheters were placed, filled with 10 mL and forcibly removed to

assess the effects of the first pullout on the residual strength of the bladder neck. These secondary measurements were similarly measured with the force gauge. Only two measurements were done on each cadaver to minimize the risk of tissue damage affecting the results. The randomization of the cadavers and the catheters was done using number sequences generated using www.random.org. The pull-out force data was compared using an unpaired t test.

Results

In the initial phase of the study, 4 catheters were filled with 5 mL and 3 catheters were filled with 10 mL and the force required to pull the inflated balloons out of the bladders was recorded. The mean force required to remove a catheter with the balloon filled with 5 cc of water was 1.24 kg whereas the mean force required to remove a catheter with 10 mL was 3.82 kg (p=0.012, range: 1.02 to 4.92 kg, mean difference -2.58, 95% CI -4.24 to -0.92). In the secondary phase of the study, mean force required to remove a catheter with the balloon filled with 10 mL after a 5 mL filled balloon had previously been pulled out was 2.54 kg. This represented a 33% reduction is force (p=0.03, range 1.02 to 2.95 kg, mean difference -1.30, 95% CI -2.45 to -0.15).

Discussion

Establishing the Foley catheter balloon fill volumes required to maintain enough resistance to keep the catheter from falling out of the bladder is an important piece of information to know when designing urinary catheter-related research protocols. Our current study in female cadavers demonstrates a similar mean force required to remove a catheter with the balloon filled with 10 mL as Wu et al., demonstrated in male cadavers (3.84 kg vs. 3.40 kg respectively [2]). In adult men and women, a balloon filled with 10 mL of sterile water has been accepted as sufficient to keep a Foley catheter in place without clear scientific evidence for the basis of this standard. The reduction of force needed to remove a balloon filled with 10 mL after a balloon-filled had previously been pullout out reflects the intuitive conclusion that pulling a balloon-filled catheter through a urethra does cause some damage to its elasticity and integrity though the extent and duration of this effect cannot be determined.

Study limitations include our small sample size, our use of only one catheter type and use of cadavers rather than live subjects. It is possible that in living subjects with normally perfused tissues at normal body temperatures and natural lubricity, our data would be slightly different. However, we stand by the use of fresh, unembalmed cadavers as the closest applicable model for study. We did not design the present study for the male population because we felt Wu et al., had already provided sufficient data in that regard.

Foley catheter balloon fill volumes have been standardized without clear data indicating the basis for recommendations. This study provides the first normative data about the pull-out pressures needed to dislodge an indwelling Foley catheter in women.

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Author's Contributions

Greenberg JA: Project development, Data collection, Manuscript writing.

Ito TE: Project development, Data collection, Manuscript writing.

Disclosure of Potential Conflicts of Interest

Greenberg JA: Dr. Greenberg is a founder and investor in Emmy Medical, Inc and Nellie Medical, Inc. Both companies manufacture novel urinary drainage catheters.

Ito TE: no conflicts of interest or financial disclosures.

Informed Consent

This study only involved cadavers and was deemed IRB Exempt by the University of Louisville IRB.

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