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Pilot Study

A Pilot Study Comparing Foley Catheter and CystoSure Catheter Balloon Volumes and Pullout Forces in Female Cadavers

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Abstract

Objective

To compare CystoSure catheters with Foley catheters at differing fill volumes to determine the force needed to remove the inflated catheter balloons from female cadaver bladders with the goal of providing normative data for potential future research.

Methods and materials

Seven CystoSure catheters and seven Foley catheters were placed into the bladders of 14 randomly assigned fresh, unembalmed female cadavers. The catheters were randomly assigned to be filled with either 5 ml or 10 ml of water. The catheters were than forcibly removed and the maximum force was recorded using a force gauge.

Results

The mean force required to remove the CystoSure catheters with the balloon filled with 5 ml and 10 ml of water was 3.10 kg ± 0.8 and 5.57 kg ± 0.9 respectively. The mean force required to remove the Foley catheters with the balloon filled with 5 ml and 10 ml of water was 1.24 kg ± 0.2 and 3.82 kg ± 1.0 respectively. There was no statistically significant difference in the force needed to forcibly remove a CystoSure catheter filled with 5 ml as compared with a Foley catheter filled with 10 ml (p=0.39).

Conclusion

As compared with an ovoid Foley catheter balloon filled with 10 cc of sterile water, a CystoSure catheter with a low-profile, open-ended, "pancake-shaped" balloon filled with only 5 cc of sterile water demonstrates a similar pullout force needed to forcible remove the balloon from the bladder through the urethra of unembalmed female cadavers.

Keywords: Bladder; Catheter; CAUTI; CystoSure; Foley; Pullout

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Introduction

Urinary catheterization and drainage is universally common practice in modern health care. However, resultant Catheter Associated Urinary Tract Infections (CAUTI's) pose a significant iatrogenic risk with ~250,000 infections per year in the US at an estimated cost of ~$250 million [1]. Solutions are needed but significant in-roads to solving this problem have been limited as recently demonstrated by a review showing a lack of effect of the Surgical Care Improvement Project (SCIP) interventions on urinary tract infections [2]. In 2015, the CystoSure urinary catheter was introduced in the United States as a novel device designed to allow a cystoscope to pass through the indwelling catheter to enable a cystoscopic examination of the bladder without removing the catheter. With its patented low-profile, open-ended, "pancake-shaped" balloon, CystoSure was designed to require lower balloon filling volumes than a traditional Foley catheter's ovoid-shaped balloon offering the additional benefit of reduced bladder mucosal trauma [3] and the potential for lower CAUTI rates.

In the most commonly used adult versions of Foley catheters, the manufacturers typically recommend filling the balloons with 10 ml of sterile saline [4]. Yet, despite the ubiquity of Foley catheters and almost a century of use in healthcare, only one study by Wu et al., quantified the retention forces generated by a 10 ml balloon, and this study was performed exclusively in male cadavers [5]. Recently, Ito et al., studied balloon volumes and pullout forces in female catheters and demonstrated 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) [6]. In this pilot study, we compare CystoSure catheters with Foley catheters (Figure 1) at differing fill volumes to determine the force needed to remove the inflated catheter balloons from female cadaver bladders with the goal of providing normative data for potential future research.

Methods and Materials

Seven 16 Fr 100% silicone CystoSure catheters (Emmy Medical, Inc., Holliston, MA) and seven 16 F 100% silicone Foley catheters (CR Bard, Inc., Murray Hill, NJ) had their dimensions measured with 5 ml and 10 ml of water and were then placed into the bladders of 14 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 only involved cadavers and was deemed IRB Exempt by the University of Louisville IRB. The *ex-vivo* placed

catheters were than randomly assigned to be filled with either 5 ml or 10 ml of water. The catheters were then forcibly removed and the minimum force was recorded using a force gauge (Force One FDIX, Wagner Instruments, and Greenwich, CT). The randomization of the cadavers and the catheters was done using number sequences generated using www.random.org. The pullout force data was compared using an unpaired t test.

Figure 1: 16 Fr. Foley catheter (left); 16 Fr. CystoSure catheter (right).

Results

4 CystoSure catheters and 4 Foley catheters were filled with 5 ml and 3 CystoSure catheters and 3 Foley 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 the CystoSure catheters with the balloon filled with 5 ml and 10 ml of water was 3.10 kg ± 0.8 and 5.57 kg ± 0.9 respectively. The mean force required to remove the Foley catheters with the balloon filled with 5 ml and 10 ml of water was 1.24 kg ± 0.2 and 3.82 kg ±1.0 respectively. A comparison of the two catheters with varying volumes is detailed in table 1. There was no statistically significant difference in the force needed to forcibly remove a CystoSure catheter filled with 5 ml as compared with a Foley catheter filled with 10 ml (p=0.39).

Conclusion

Establishing the urinary catheter balloon fill volumes required to maintain enough resistance to keep the catheter from falling out of the bladder when it is untethered or accidently pulled is an important piece of information to know in designing urinary catheter-related research protocols. In adult men and women, a Foley catheter balloon filled with 10 cc of sterile water has been accepted as sufficient to keep a Foley catheter in place with only limited scientific evidence of this standard. Our current study in female cadavers demonstrates a similar mean force required to remove a Foley catheter with the balloon filled with 10 ml and a CystoSure catheter with the balloon filled with only 5 cc (3.82 kg vs. 3.10 kg respectively) and appear consistent with Wu's data from male cadavers. These results are not surprising if one considers the urethral-vesicle junction as a funnel and the balloon as a plug. From a biomechanical perspective, as force is exerted outwards to remove the balloon, if the balloon maintains its radial diameter rather than distorting vertically, it will generate more resistance to removed. Based on the design specifications with the CystoSure balloon maintaining a doughnut shape as compared with the vertically-expanding Foley catheter, we hypothesize that this explains the observed removal forces.

Study limitations include the small sample size and the 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., [5] had already provided sufficient data in that regard.

	CS 10ml	Foley 10ml	CS 5ml	Foley 10ml	CS 5ml	Foley 5ml
Mean force	5.57 ± 0.9	3.82 ± 1.0	3.10 ± 0.8	3.82 ± 1.0	3.10 ± 0.8	1.24 ± 0.2
p value	0.094		0.388		0.015*	
Mean difference	1.75		-0.71		1.87	
Range	2.92 to 6.42		2.28 to 4.92		1.02 to 3.82	
C.I.	-0.47 to 3.97		-2.76 to 1.34		0.59 to 3.15	
Mean height	18.1 ± 1.3	24.4 ± 2.6	14.1 ± 1.2	24.4 ± 2.6	14.1 ± 1.2	20.3 ± 0.8
p value	0.0003*		0.0001*		0.0001*	
Mean difference	-6.36		-10.35		-6.21	
Range	17.5 to 26.2		12.0 to 26.2		12.0 to 15.5	
C.I.	3.72 to 9.01		7.7 to 13.01		4.85 to 7.58	
Mean width	29.3 ± 0.8	26.4 ± 0.9	23.5 ± 0.5	26.4 ± 0.9	23.5 ± 0.5	21.1 ± 0.3
p value	0.0172*		0.0094*		0.0027*	
Mean difference	2.87		-2.93		2.37	
Range	25.5 to 30.9		20.7 to 23.9		20.7 to 23.9	
C.I.	-4.896 to -0.837		1.197 to 4.670		-3.359 to -1.374	
Mean W/Ht	1.6 ± 0.01	1.0 ± 0.1	1.7 ± 0.2	1.0 ± 0.1	1.7 ± 0.2	1.0 ± 0.1
p value	0.0004*		0.005*		0.0044*	
Mean difference	0.57		-0.67		0.67	
Range	0.97 to 1.65		0.97 to 1.91		0.99 to 1.91	
C.I.	-0.7147 to -0.4186		-0.9965 to -0.3369		-0.9906 to -0.3494	

Table 1: Mean pullout forces (kg) and balloon dimensions (mm) at varying balloon volumes between CystoSure (CS) and Foley catheters.

Note: Denotes statistically significant values (p<0.05).

Summary

As compared with an ovoid Foley catheter balloon filled with 10 cc of sterile water, a CystoSure catheter with a low-profile, open-ended, "pancake-shaped" balloon filled with only 5 cc of sterile water demonstrates a similar pullout force needed to forcible remove the balloon from the bladder through the urethra of unembalmed female cadavers.

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