Silicon foleys: Are you deflating us? A comparative study of various silicon foleys catheter's deflation rates

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Abstract
Introduction: Premature deflation and spontaneous expulsion of the Foley catheter is detrimental to outcome of surgeries. Previous studies have compared latex with silicon and also evaluated various types of fluid used to inflate the bulbs of Foley catheters. We hypothesized that deflation rates would vary between different brands of Foleys available and the rate would also vary with time.
Materials and Methods: Eight different brands of 14-French 45 cm long Foley silicone catheters were used. Bulbs were inflated with the 10 mL of saline solution. The widest point, vertically and horizontally was measured. Each bulb was completely submerged into a sterile urine bath at 38°C. Every alternate day bulbs were removed from the urine bath. Vertical and horizontal measurements were recorded for each bulb and the catheters were replaced in the bath. This procedure was repeated for 28 days.
Results: The correlation of "deflation rates of silicon Foley's bulb" provided by 7 companies was calculated with respect to each other and with respect to time. It was found that all the different silicon Foleys showed significant positive correlation with each other ($p<0.01$) and thus, none was better or worse than the other. Although all silicon Foleys catheter deflate over time, the deflation starts usually after initial 6-8 days.
Conclusion: The deflation of bulb and spontaneous expulsion of Foleys does not vary among commonly available brands. Additional measures like hitching the catheter to glans penis may be used if prolonged (greater than 7 days) catherization is necessary.

Keywords: Foley catheter, Silicone catheter, Deflation rate, Hitching, Brands of silicone.

Introduction
The Foley catheter is commonly used in clinical practice for monitoring patients with urinary tract disease. Specifically, Foley catheters are used to assess urinary output or divert urine in cases of urethral obstruction. They are used in surgeries like urethroplasty, adult hypospadias repair, radical prostatectomy, neobladder etc. 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 hampers patient management. Early deflation and sudden removal are detrimental to outcome of surgeries.

Previous studies have evaluated the type of fluid used to inflate the bulbs of Foley catheters. Silicone Foley catheters manufactured by Dover and Travenol, were used to determine which type of filling solution should be used to inflate the bulb. Silicone bulbs submerged in urine, with sterile water as an inflation fluid, had more fluid loss compared with bulbs filled with 0.9% sodium chloride (NaCl) solution. A study of Foley catheters made of latex; the results showed significant difference in the final bulb volume when filling the bulbs with sterile water and 0.9% NaCl solution.[3]

Studies have also compared latex and silicon foleys catheter and found no difference in complications for short term drainage.[1]

There is, however no study to compare the efficacy of silicon Foleys provided by various companies available with us. We attempt to determine comparative deflation rates of various silicon Foleys available. There is no record of the rate of deflation with respect to time. Our objective was to compare deflation rates of silicone Foley catheter bulb. Normal saline was used. We hypothesized that deflation rates would vary between different brands of Foleys and with respect to time.

Materials and Methods
A total of 7 14-French 45 cm long Foley silicone catheters were use. 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, bulbs were inflated with the manufacturer's recommended volume of 10 mL of normal saline solution. Using a calliper, the widest point was identified by eye and each bulb's maximal diameter, vertically and horizontally was measured and recorded. Upon completion of the initial data collection, each catheter's bulb was completely submerged into a sterile urine bath at 38°C. Sterile urine bath was prepared with human urine and levofloxacin antibiotic added to prevent growth of bacteria. The osmolarity of the urine was measured with a micro osmometer at our hospital's lab. The warm urine baths were prepared using water heaters available for aquariums. A thermometer was placed in the water bath to monitor the maintenance of the 38°C temperature.

Every alternate day bulbs were removed from the urine bath. Vertical and horizontal measurements were recorded for each bulb and the catheters were replaced in the bath. This procedure was repeated for 28 days. The authors confirm the availability of, and access to, all original data reported in this study.

Statistical analysis

Data so collected was tabulated in an excel sheet, under the guidance of statistician.

Volume of the bulb was calculated by the formulae:

Volume of ellipse (bulb) – Volume of cylinder (Foleys tube)

$$\frac{4}{3}\pi H^2 V - \pi r^2 H$$

H = Horizontal diameter

V = Vertical diameter

r = Radius of the foleys tube

The means and standard deviations of the measurements per group were used for statistical analysis (SPSS 24.00 for windows; SPSS inc, Chicago, USA). Pearson correlation was used to assess the relation between the different groups. Pearson correlation coefficient also referred to as Pearson's r, the Pearson product-moment correlation coefficient (PPMCC) or the bivariate correlation, is a measure of the linear correlation between two variables X and Y. According to the Cauchy–Schwarz inequality it has a value between +1 and −1, where 1 is total positive linear correlation, 0 is no linear correlation, and −1 is total negative linear correlation. The level of significance (p) was set at $p < 0.05$.

Results

The measured osmolarity of the urine was 720 milliosmoles/l. Out of the 7 catheters, one catheter bulb ruptured while taking readings with calliper. This catheter was thus excluded from the study. Mean diameters of the Foley bulbs for each group on days 0, 2, 4, 6, 8, 10 till day 28 are mentioned in the table. The change of volume of foleys bulb provided by various companies (available with us) showed significant positive correlation with each other ($p<0.01$). The deflation essentially started after initial 6-8 days.

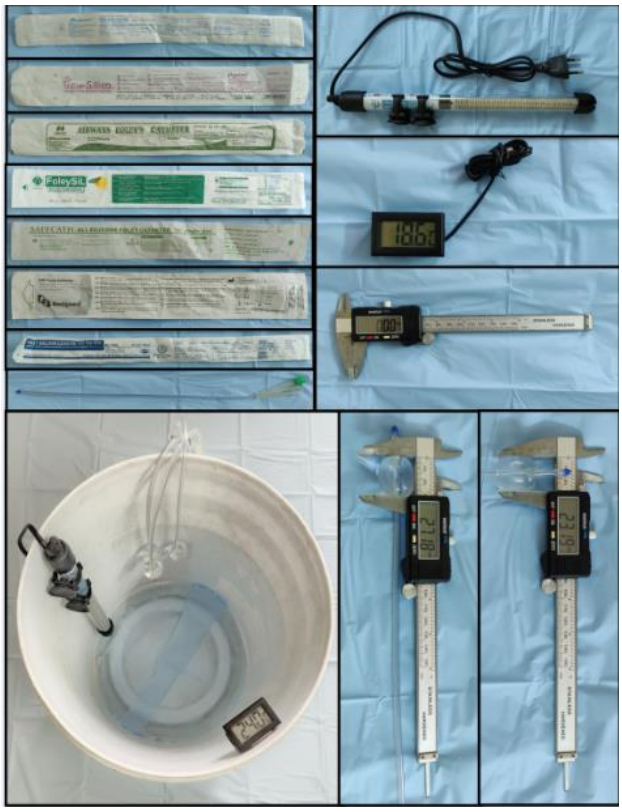

Fig. 1:

Table 1:

		Romsons	La-Med	Airways	FoleySil	Safecath	BactiGuard	Rousch
July 15'2019	Vertical diameter (mm)	2868	2800	2902	2990	2850	2712	2895
	Horizontal diameter	2650	2394	2594	2078	2725	2704	2680
	Volume (cubic cm)	84321627.14	67185312	78108269	54054290	88602499	83017788	
July 17'2019	Vertical diameter (mm)	2850	2800	2894	2990	2846	2709	2895
	Horizontal diameter	2650	2380	2594	2068	2724	2698	2680
	Volume (cubic cm)	83792411.91	66401816	77892947	53535289	88413219	82558347	
July 19'2019	Vertical diameter (mm)	2828	2794	2886	2986	2840	2705	2892
	Horizontal diameter	2650	2364	2594	2050	2720	2690	2674
	Volume (cubic cm)	83145593.29	65371636	77677624	52537017	87967905	81948295	
July 21'2019	Vertical diameter (mm)	2804	2790	2878	2984	2835	2702	2890
	Horizontal diameter	2648	2354	2592	2042	2718	2684	2670
	Volume (cubic cm)	82315582.16	64726947	77342899	52092856	87683942	81492653	Deflated
July 23'2019	Vertical diameter (mm)	2784	2788	2874	2980	2832	2699	
	Horizontal diameter	2648	2350	2571	2028	2710	2679	
	Volume (cubic cm)	81728452.47	64460919	75988973	51312129	87076292	81099169	
July 25'2019	Vertical diameter (mm)	2760	2782	2869	2980	2829	2698	
	Horizontal diameter	2646	2332	2554	2021	2706	2675	

	Volume (cubic cm)	80901550.39	63340606	74856926	50958514	86727460	80827214	
July 27'2019	Vertical diameter (mm)	2746	2779	2862	2978	2829	2695	
	Horizontal diameter	2645	2310	2535	2011	2706	2671	
	Volume (cubic cm)	80430351.77	62084115	73567365	50421609	86727460	80496062	
July 29'2019	Vertical diameter (mm)	2721	2761	2856	2966	2826	2689	
	Horizontal diameter	2640	2301	2510	2002	2701	2662	
	Volume (cubic cm)	79397070.17	61202284	71972284	49769944	86315625	79776502	
July 31'2019	Vertical diameter (mm)	2698	2746	2851	2949	2800	2681	
	Horizontal diameter	2636	2286	2492	1993	2680	2655	
	Volume (cubic cm)	78487561.72	60078761	70819512	49040763	84196824	79121398	
August 1'2019	Vertical diameter (mm)	2682	2722	2844	2932	2781	2676	
	Horizontal diameter	2630	2270	2469	1985	2663	2648	
	Volume (cubic cm)	77667325.35	58722943	69347594	48367410	82567932	78557952	
August 3'2019	Vertical diameter (mm)	2665	2703	2836	2905	2761	2669	
	Horizontal diameter	2622	2253	2446	1979	2644	2641	
	Volume (cubic cm)	76706234.75	57442905	67870141	47632741	80808564	77938754	
August 5'2019	Vertical diameter (mm)	2640	2688	2829	2980	2749	2660	
	Horizontal diameter	2618	2237	2419	1975	2617	2639	
	Volume (cubic cm)	75754997.38	56315662	66216207	48665177	78822510	77558339	
August 7'2019	Vertical diameter (mm)	2619	2669	2824	2961	2733	2651	
	Horizontal diameter	2610	2223	2401	1973	2594	2633	
	Volume (cubic cm)	74693805.67	55219880	65119135	48257011	76992362	76944844	
August 9'2019	Vertical diameter (mm)	2594	2641	2820	2939	2708	2642	
	Horizontal diameter	2605	2217	2386	1971	2568	2631	
	Volume (cubic cm)	73697626.31	54346020	64216937	47801406	74766450	76567169	
August 11'2019	Vertical diameter (mm)	2570	2627	2817	2825	2612	2631	
	Horizontal diameter	2395	2198	2365	1968	2543	2628	
	Volume (cubic cm)	61718047.01	53135332	63024402	45807488	70718648	76074595	

		Romsons	**La-Med**	**Airways**	**FoleySil**	**Safecath**	**BactiGuard**
Romsons	Pearson Correlation	1	.887**	.880**	.882**	.943**	.877**
	Sig. (2-tailed)		.000	.000	.000	.000	.000
La-Med	Pearson Correlation	.887**	1	.996**	.960**	.953**	.997**
	Sig. (2-tailed)	.000		.000	.000	.000	.000
Airways	Pearson Correlation	.880**	.996**	1	.949**	.952**	.992**
	Sig. (2-tailed)	.000	.000		.000	.000	.000
FoleySil	Pearson Correlation	.882**	.960**	.949**	1	0.881**	0.969**
	Sig. (2-tailed)	.000	.000	.000		.000	.000
Safecath	Pearson Correlation	.943**	.953**	.952**	0.881**	1	.942**
	Sig. (2-tailed)	.000	.000	.000	.000		.000
BactiGuard	Pearson Correlation	.877**	.997**	.992**	0.969**	.942**	1
	Sig. (2-tailed)	.000	.000	.000	.000	.000	

**. Correlation is significant at the 0.01 level (2-tailed), *. Correlation is significant at the 0.05 level (2-tailed).

Discussion

Urethral catheterization is one of the most frequent invasive procedures performed in hospitalized patients.[4] Indwelling urinary catheters, which are used in 16– 25% of hospitalized patients, have been an integral part of medical care since the invention of the Foley catheter, a common type of indwelling catheter in 1930.[5] Foley catheters have been widely used for short- or long-term bladder drainage, relief from obstructive uropathy in both males and females in all ages and in various surgeries in post-operative period. Once placed, the balloon is distended with a solution; the inflated balloon then aids retention of the catheter in the urinary bladder. Patient conditions sometimes dictate use of a Foley catheter for extended periods for example:

1. Surgeries like urethroplasty, adult hypospadias repair, radical prostatectomy, neobladder etc.
2. Urethral pathology or treatment of renal insufficiency where the clinician is awaiting stabilization of the patient.
3. Assisting in nursing care for paralyzed patients and patients in post-operative period.

Latex vs silicone: In studies comparing latex vs silicon, it became evident that for short term drainage, the complication rate was similar in both the catheters[1] However for long term drainage, latex foleys caused significantly more inflammatory reaction than silicone foleys.[6].

Normal saline vs sterile water vs air vs glycine: In an in vitro study by Hui et al[7] comparing the rate of deflation failure of 4000 latex Foley catheter balloons using either sterile water or normal saline as a filling solution, it was shown that there was no significant difference in the rate of deflation failure of Foley catheter balloons by using either sterile water or normal saline. The results of the studies by Hui et al[7] and Huang et al[3] have indicated that the aspirated deflation volume for sterile water was significantly less than that of the normal saline at the end of study.

Crystal formation: Normal saline may result in crystal formation and blockage of the balloon inflation channel. The solubility of sodium chloride in water at 37-degree Celsius is approximately 36 g per 100 mL of water, which is approximately 40 times greater than the concentration of normal saline (0.9%, i.e. 0.9 g per 100 mL of water) Hence, the chance of crystallization is quite low for normal saline at body temperature.[7]

Inlet valve leak: 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. 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. 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.

Keeping in mind the above experience, silicon foleys are used for long term drainage and filled with normal saline. We compared the different brands of silicon and the chronology of deflation. Measurement days were selected based on clinical experience and previous studies.

Our study found out that

1. Although all silicon foleys catheter deflate over time with respect to latex foleys, the deflation starts usually after initial 6-8 days.
2. Over time all silicon foleys catheter deflate regardless of the brand.

This breaks the myth of varying deflation rated with different types of catheters. Additional measures like hitching the catheter to glans penis may be used if prolonged (greater than 7 days) catherization is necessary as that is the time deflation starts. This has several clinical implications:

1. In patients in whom the spontaneous expulsion can significantly reduce the chances of success of surgery, simple hitching to glans can help preserve the anastomosis and graft and improve surgical outcome.
2. Bedridden patients at home care can avoid repeated visits to clinics before the date of catheter change and thus prevent additional cost implications on patient.
3. Add to the unnecessary avoidable workload at hospitals.

Conclusion

Patient conditions sometimes dictate use of a Foley catheter for extended periods. The deflation of bulb and spontaneous expulsion of Foleys does not vary among commonly available brands of silicon foleys. Additional measures like hitching the catheter to glans penis may be used if prolonged (greater than 7 days) catherization is necessary.

Conflict of Interest

The authors declare that there is no conflict of interests

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None.

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