GAVIN PUBLISHERS

Journal of Urology and Renal Diseases

Lockhart J, et al. J Urol Ren Dis 2017: J125.

DOI: 10.29011/2575-7903.000025

Research Article

The Lotus Catheter: a Non-Balloon Novel Urethral Catheter- a Prospective Study

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Citation: Lockhart J, Boyle A, Kidd LC, Shah B, Beilan J, et al. (2017) The Lotus Catheter: a Non-Balloon Novel Urethral Catheter- a Prospective Study. J Urol Ren Dis 2017: J125. DOI: 10.29011/2575-7903.000025

Received Date: 17 February, 2017; Accepted Date: 20 February, 2017; **Published Date:** 27 February, 2017

Abstract

Introduction and Objectives: The design of the standard urinary Foley catheter (FC) has several limitations due to the presence of a balloon. In addition to trauma (inflation in the urethra during placement or accidental removal), the FC has also been associated with some degree of residual urine, which contributes to increased risk of urinary tract infections. The Lotus catheter was designed to have a deployable Malecot-like soft-winged retention mechanism that replaces the inflatable balloon of a FC, such modifications, not only improves urinary drainage by allowing the lumen to rest at the bladder neck, but also ensuring safety due to compressibility within the urethra. The purpose of this study is to determine the performance of this catheter in a clinical setting.

Methods: Patients anticipated to require less than 5 days of urinary drainage between July 1, 2015 and July 31, 2016 were consented and underwent placement of a Lotus catheter; data were collected prospectively in an IRB-approved database. Following insertion of the Lotus catheter, ease of placement and removal was recorded, as well as patient discomfort. Additionally, a post catheter residual volume was obtained using a bladder scanner. Patients were followed for complications, such as discomfort, catheter trauma and/or symptomatic urinary infection

Results: 50 patients underwent Lotus catheter placement, 15 male and 35 female. All inserters noted ease of insertion as being extremely easy. No gross hematuria was reported with any insertion and the mean PVR following catheter insertion was 4.8 mL, with PVRs >0ml noted in only 8 patients. The median discomfort level at the time of Lotus removal was 2 out of 10, using Wong-Baker scale. Two catheters were dislodged without deactivation, with no resulting hematuria or patient discomfort. No UTIs were detected in any patient.

Conclusion: To our knowledge, this is the first study evaluating the Lotus catheter in a clinical setting. Preliminary data show the Lotus catheter is safe, easily inserted, and drains the bladder with minimal or no urinary residual. There appears to be an additional benefit of limiting urethral trauma associated with accidental removal. The Lotus catheter may be an ideal option for patients with uncomplicated urethras who require short-term catheter placement.

Keywords: Lotus; Catheter; Balloon; Post-Void Residual

Introduction

Urethral catheterization (UC) is a common practice in the healthcare setting, with over 30 million catheters being inserted annually in the United States [1]. A majority of these are performed with standard balloon Foley catheters, which have remained highly popular since coming onto the market in 1933 [2]. However, despite its frequency of use, UC has been shown to be associated with a number of complications, including UTI, representing the fourth most common healthcare-associated infection [3], as well as urethral trauma [2,4-7]. As such, UC has been the subject of much investigation into reducing these problems and avoiding unnecessary catheterization in the inpatient population. Some of these complications are seemingly unavoidable in catheterization, given its inherently invasive nature, while others appear to relate more to the Foley catheter's balloon-based design. A 2013 review by Dellimore et al. concluded that the top five most frequent complications as a result of UC were due to mechanical interaction of the catheter and the urethra, highlighting the need for more ideal

catheter design. These complications included symptomatic bacterial infection, severe mechanical trauma, hypersensitivity to latex, urethral stenosis/stricture, and calculi/encrustations/blockage [8]. In fact, one retrospective study found that UC-related trauma was actually a more frequent occurrence than UC-associated UTI, at 0.5% versus 0.3% of Foley catheter days [5].

Further studies have sought to elucidate the incidence of UC-related urethral injury, specifically. A prospective investigation of two tertiary academic centers by Davis et al. showed a 6.7 per 1000 rate of iatrogenic UC complications, estimated to cost more than $371,000 during the 6-month study period. They also noted that the majority of these issues were a function of the presence of a catheter balloon, specifically its inflation intraurethrally [7]. A similar prospective study noted an incidence of 3.2 injuries per 1000 patients at their single institution, which dropped to 0.7 per 1000 after implementation of a hospital-wide nursing education program emphasizing proper inflation of the Foley balloon, again, avoiding doing so inside of the urethra [6]. While this study focused on improving nursing care, problematic catheter design was a requisite to development of these injuries. Issues specific to the Foley balloon have been investigated, as well. Wu et al. determined that catheter balloon filling pressures were 1.9-times higher in a cadaver urethra versus bladder. They determined that significant force was required to forcibly remove an inflated Foley catheter from the bladder. Interestingly, in latex but not silicon catheters the neck of the balloon port acted as a pressure valve that expanded over a pressure threshold, while some silicon catheters burst at similar removal forces.

These authors urged the importance of better catheter design to avoid these urethral injuries [4]. Furthermore, transvaginal ultrasound has been used to demonstrate the poor emptying capacity of Foley catheters versus straight catheters, with mean PVRs of 77 mL and 0 mL, respectively [9].Over the years, different designs have been investigated in attempts to minimize UC morbidity rates, including impregnation of catheter surface with lubricating and antimicrobial tips, as well as the dual balloon catheter [2]. Unfortunately enough, these variations still share the disadvantages inherent to a balloon-based model. The Lotus catheter seeks to minimize these pitfalls with its deployable Malecot-like soft-winged retention mechanism, effectively replacing the inflatable balloon of a standard Foley catheter (Figure 1a-d).

Figure-1a

Figure-1b

Figure-1c

Figure-1d

Figure 1a-d: Picture of Lotus Catheter Design

Ideally, this places the lumen of the catheter at the level of the bladder neck, improving urinary drainage, due to its larger openings. It also offers improved safety due to its compressibility in the urethra in the event of premature activation of the wings or accidental forceful dislodgement. We sought to observe and document the Lotus catheter in a clinical setting, representing the first assessment of its performance in the literature to date.

Materials & Methods

Patients were identified who were anticipated to require less than five days of drainage via urinary catheter between July 1st, 2015and June 31st, 2016. They were educated on the risks and benefits of catheter placement, written consent was obtained and the Lotus catheters were placed. Insertion was performed by experienced healthcare providers, who recorded ease of placement and removal on a subjective scale of one to seven, seven representing absolute ease of insertion/removal and one representing extreme difficulty. Patient discomfort was recorded on a scale from zero (absolute comfort) to ten (extreme discomfort). After removal, patients underwent bedside bladder ultrasound to determine post-void residual urine volume. Duration of time needed for catheter insertion (in seconds), as well as presence or absence of gross hematuria were also recorded. Follow-up was performed to monitor for development of complications. Six patients in the study reported previous severe discomfort from a balloon catheter previously dislodged from the bladder. All patient data was collected in our Institutional Review Board (IRB) approved prospective database.

Results

Our prospective cohort consisted on 50 patients at a single tertiary referral institution (Table 1).

Mean Time for Insertion (sec)	4
Mean Discomfort Rating (#/10)	0
Mean Ease of Insertion (#/7)	7
Gross Hematuria	
Present	n=0 (0%)
Absent	n=50 (100%)
Complications	None

Table 1: Lotus Catheter Insertion Results.

Summarizes the results of Lotus catheter insertions. Mean time needed for insertion was 4 seconds, with a range of 1 to 20 seconds. Mean discomfort rating was 0 out of 10. Mean ease of insertion was 7 out of 7, extremely easy. No gross hematuria was demonstrated post insertion in the cohort, with no other complications noted at follow-up (Table 2).

Mean Time for Removal (sec)	3
Mean Discomfort Rating (#/10)	2
Ease of Removal (#/7)	7
Mean PVR after Removal	4.8 mL
Complications	n=3 (6%)
Accidental Removal	n=2 (4%)
Antispasmotic Required	n=1 (2%)

Table 2: Lotus Catheter Removal Results.

reports similar results for Lotus catheter removal. Average removal time was 3 seconds (1 - 10 seconds). Mean discomfort was 2 out of 10, ease of removal 7 out of 7, with a mean PVR of 4.8 mL (ranging from 0 to 76 mL). A single patient had ascites, compromising accurate PVR recording, and was excluded from this measurement. In the entire cohort, 3 patients experienced complications, including one accidental removal, which caused no subsequent injury, and a case of bladder spasming, requiring use of anticholinergic medication.

Discussion

Foley catheters have remained the standard for urinary catheterization in numerous care centers since they originally gained popularity. However, investigation into their use has elucidated several problems associated with their design. They allow for higher residual volume of urine in the bladder, following their insertion, given the position of the balloon in the bladder and the relatively small opening for drainage. This can lead to additional morbidity, especially in the form of infection, one of the most common sources of healthcare-associated infections in the country, which can further lead to encrustations and kidney stones. Foley catheters also cause mechanical complications when accidentally inflated within the urethra or forcefully removed, which can lead to long-term issues such as stricture or stenosis, which contribute a great burden of disease to affected patient. Six patients reported significant events with previous balloon catheters. Studies have repeatedly highlighted the limitations of the Foley catheter structure, hailing the need for smarter design. While attempts have been made to improve catheters, such as using novel coatings or even a double balloon model, we have yet to see a design that removes the balloon aspect entirely while still satisfactorily fulfilling the basic requirements of a urinary catheter. We believe that the Lotus catheter may have succeeded in this goal.

Based on our results, the Lotus catheter appears to avoid the pitfalls of a standard Foley catheter. It drains the bladder effectively, as evidenced by a mean post-void residual of <5mL. This would theoretically lower the risk of UTI in this population, although formal studies would need to be performed to specifically

address this. There were also no recorded complications during or after insertion. The two instances of accidental removal resulted in no apparent trauma to the urethra and no gross hematuria, followed by simple reinsertion. The only other complication was that of bladder spasms, a relatively benign occurrence that was resolved with a short course of anticholinergic medication and could have been related to the surgical procedure itself. Patient discomfort was low, and insertion/removal were noted to be technically easy to perform, requiring very little time. The only negative possible event for the Lotus catheter would be the easier dislodgement of the catheter as compared to a balloon catheter. However, that can be prevented with more effective catheter fixation to the thigh and if catheter is accidentally removed, it can be easily reinserted.

To our knowledge, this is the first investigation into the performance of the Lotus catheter in a clinical setting. However, despite our promising results, our study is not without limitations. One such example is our small sample size and the single institution setting. Another restriction is the possible referral bias of working at a tertiary care center. These can all lead to poor sampling, something that could be rectified by future, larger studies involving multiple centers and patient acuity levels. Another limitation is the subjective nature of our scoring system for ease of removal and insertion, allowing for inter-user variability. On the same token, patient pain scores are also highly subjective, yielding a similar problem. Future directions after this study would likely be direct comparison of the Lotus catheter against the Foley, ideally in the form of a blinded randomized-controlled trial. An expanded patient population, both in number and sampling distribution would be optimal, perhaps in concert with additional healthcare centers.

Conclusions

Foley catheterization, despite its popularity, is a source of morbidity and even mortality for some patients in whom it is used, constituted mainly by either urinary tract infection secondary to poor emptying, or trauma from inflation of the balloon in the urethra or forceful removal. These can all be attributed to the Foley's balloon-based design. We suggest that the Lotus catheter, by replacing the balloon mechanism for a Malecot-like model, avoids these common shortcomings, empties the bladder completely, with a low rate of complication, is easy to insert and remove, and is safe in the event of urethral inflation or accidental removal.

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