

Impact of Catheter Characteristic on Complications Associated with Clean Intermittent Catheterization: Review of the Literature and Our Experience

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Received: September 15, 2020; Published: January 27, 2021

Abstract

Clean intermittent catheterization is considered the gold standard for neurogenic bladder management, and long-term monitoring shows that there are certain complications associated with this procedure. The most important and frequent complication is urinary tract infection followed by urethral bleeding, urethral stricture, and false passages. Because of catheter-related complications, patients face low adherence, so clean intermittent catheterization may be seen as a task they must perform rather than as a technique that brings choice and freedom in resolving urinary problems. Several studies assessed the impact of different catheter features in the incidence of urethral complications, urinary tract infection and patient satisfaction. The aim of this study was to investigate impact of catheter characteristics on urethral complications and patient's satisfaction to a newly developed hydrophilic-coated catheter (LentisCath™, Lentismed, Croatia) with comprehensive review of the literature.

Keywords: Clean Intermittent Catheterization; Mitrofanoff Procedure; Urethral Complications; No-Touch Technique; Hydrophilic Layer; Ready to Use; Discretion; Rigidity; Drainage Eyes; Patient Satisfaction

Introduction

Before the development of modern methods of neurogenic bladder management, inadequate treatment resulted in high intravesical pressure, vesicoureteral reflux, and chronic colonization of bacteria and infections, resulting in high rate of complications. Traditionally, intermittent catheterization was performed using a sterile technique, which was expensive, time-consuming, and inconvenient. The introduction of a clean technique has facilitated the management of the neurogenic bladder [1]. Despite the fact that clean intermittent catheterization (CIC) is considered the gold standard for managing neurogenic bladder, long term follow-up shows that there are certain complications associated with CIC [2]. Urinary tract infection (UTI) is the most important and frequent complication. Trauma from catheterization occurs regularly, but lasting effects are more limited. However, the prevalence of urethral strictures and false passages increases with longer use of CIC [3]. Complications associated with CIC exist and several studies have examined the impact of different catheter features on the incidence of urinary tract infection, urethral bleeding, structures and false passages associated with urethral trauma.

Designs and characteristics of catheters used in intermittent catheterization vary considerably, so evaluation and selection of products is complex. Different catheter designs and techniques may affect complications associated with intermittent catheterization. The aim of this paper was to review the literature on urethral complications and quality of life related to catheter characteristics in patients performing CIC, and to evaluate our experience with using a newly developed hydrophilic-coated catheter (LentisCath™) in patients performing

CIC. A greater understanding of catheter impact on urethra and patients' satisfaction is essential to ensure good adherence and outcome of clean intermittent catheterization and improve quality of life.

Complications of CIC associated with catheter characteristics

Catheter characteristic and urinary tract infection

Urinary tract infection (UTI) is the most common complication associated to CIC and constitutes a major reason for concern in patients and their clinicians and caregivers. Asymptomatic bacteriuria is frequent in patients performing CIC and it occurs in approximately 75 % of patients [4]. At least 25% patients suffer two or more symptomatic UTI episodes per year [3]. According to Siroky (2002) the annual incidence of UTI in patients with the neurogenic bladder is high, with an overall rate of 2.5 episodes per patient per year [5]. UTI is an important complication following Mitrofanoff procedures. The risk factors for UTI are associated with the use of clean intermittent self-catheterization and intestinal augmentation [6]. On the other hand, Mitrofanoff catheterization was found associated with fewer episodes of frequent urinary tract infection and greater adherence in comparison with urethral catheterization [7].

There are some reviews that compared catheter designs, materials and techniques in terms of coated or uncoated catheter; single-use or multiple-use catheters; self-catheterisation or catheterisation by others (such as parents or carers) associated with UTI in long-term intermittent catheterisation. They could not confirm the incidence of symptomatic UTI is affected by any catheter design because of inadequate evidence. Patients should be offered a choice between different types of medical devices [8-10]. However, some studies argue that contamination with microorganisms and other debris were found on reused catheter while no microorganism contamination was seen in single-use hydrophilic-coated catheters. They stated that catheter reuse may increase the risk of UTI through microbial colonization and it was noted that the cleaning procedures are commonly not sufficient for reducing microbial contamination [11]. Compared to standard uncoated PVC catheters, the use of a ready-to-use hydrophilic-coated catheter is associated with a significantly longer time to the first symptomatic UTI as well as a lower incidence of symptomatic UTIs [9,12,13]. Although there are inconsistent results in the literature, they support the use of single-use hydrophilic catheters to minimize the risk of UTI.

It has been suggested that because the hydrophilic catheters do not require manual lubrication, they are more sterile and thus less likely to cause infection. Most hydrophilic catheters are pre-packaged in sterile water, or there is a pouch of sterile water that is broken and released into the catheter package when the catheter is ready to use [14].

In patient with spinal cord injury it was found that only half of them washes their hands before starting the procedure of intermittent self-catheterization [15]. It was also reported that 32 % of patients touched the coated portion of the catheter tube during catheterization [16]. Development of new characteristics of the catheter such as no-touch grip can provide a long-term benefit to patients requiring intermittent catheterization by reducing the introduction of bacteria into the urinary tract. Catheters with no-touch grip meet the standards promoted by the European Association of Urologists (EAU) which recommends aseptic catheterization [17].

Polyvinyl Chloride (PVC) is relatively rigid and can cause discomfort for users during and after insertion. Chemical additives are used to increase the flexibility of PVC; however still some catheters are too stiff to be considered safe. Toxic additives can leach into a user's system and cause unwanted reactions [18]. There is no study examining the effect of tube stiffness/rigidity on the incidence of UTI in intermittent catheters. Plevnik, *et al.* (1985) reported that rigid and stiff catheter tube with fast and traumatic insertion can damage the urethra and cause complications [19]. A rigid catheter will distort the natural geometry of the urethra as it passes through the urethra, creating new frictional forces on the wall of the urethra. Soft and light catheters create significantly smaller differences in friction force than rigid and heavy catheters. Lane (2009) also claim that soft catheters are less likely to cause irritation of the urothelium when compared with catheters made of more rigid material [20]. It can be stated that less irritation of the urethral mucosa leads to a lower chance of developing UTI.

Catheter characteristics and trauma

Urethral bleeding episodes are frequent, affecting as many as one-third (74%) of patients under long-term intermittent catheterization and 28% after 3 months from the onset of CIC, mainly in male population [21]. The trauma of the urethra especially in men can cause false passages, meatal stenosis, and urethral stricture. Urethral stricture as a complication of clean intermittent self-catheterization in patients with neurogenic bladder has a low incidence. The study with the longest follow-up reported urethral complications rate of 25% with a mean duration of catheterization of 16 years [22]. Wyndaele (2002) reported the rate of urethral stricture using traditional polyvinyl chloride catheters reached approximately 10% [3]. In Perrouin-Verbe., *et al.* (1995) study rate of urethral stricture was 5.3%, similar to Cornejo-Dávila., *et al.* (2017) study where urethral stricture developed in 4.2% of cases [23,24]. The incidence of urethral strictures increases with a longer follow-up [24]. False passages are also considered classical complications and often occur in the case of urethral stricture, bladder-sphincter dyssynergia and enlarged prostate. However, their incidence has tended to decrease for several years because of improved nursing care and the development of new catheters [25].

Hydrophilic-coated catheters have been reported to significantly reduce urethral complications with a significant decrease in urethral bleeding episodes and microtemuria compared to standard uncoated catheters [1,9,13,26,27]. The osmolality of the hydrophilic layer is important in reducing the friction of the catheter to the urethra and thus preventing urethral damage. The longer the drainage time and the longer the catheter is inserted into the urethra, the less friction there will be when the osmolality of the hydrophilic layer is more persistent [28]. A study comparing two different catheters with a hydrophilic layer demonstrated that a catheter with higher osmolality has a significantly lower coefficient of friction when removing the catheter from the urethra [29]. Hydrophilic-coated catheters cannot be reused, cleaning technique used in reusable catheter would damage the hydrophilic layer.

Gentle introduction of the catheter, substantial lubrication of the catheter and the use of hydrophilic catheters play an important role in preventing urethral trauma. Forceful manipulations during catheter insertion and significant bleeding have been shown to be important factors in the development of urethral stricture in patients on CIC [30]. In addition to the hydrophilic layer, rigid and stiff catheter tube with fast and traumatic insertion can damage the urethra and cause complications. A rigid catheter will distort the natural geometry of the urethra as it passes through, creating new frictional forces on the wall of the urethral channel. Soft and light catheters create significantly smaller differences in friction force than rigid and heavy catheters [19,20].

The shape of the drainage eyes on the catheter tube is important, as during catheterization these are very close to the wall of the urethra, especially at the curves of the male urethra. Stickler., *et al.* (2003) demonstrated that surface lines and irregularities occur especially around the drainage eyes [31]. The results show that initial cell adhesion is due to the irregular surfaces surrounding the catheter eye-holes. Stensballe., *et al.* (2005) assume that the shape of the drainage eyes has an impact on the level of friction exerted by a catheter at withdrawal [32]. Increasing the frictional force is thought to increase the irritation of urethral mucosa, eventually causing inflammation and long-term complications [33]. However, one study showed no significant difference in withdrawal friction force measured for catheters with and without drainage eyes [28]. To avoid microtraumas of the urethral mucosa, it is recommended that the holes are rounded and have no sharp edges.

Catheter characteristic and user satisfaction

Patient adherence is a key factor for ensuring good clinical outcome, and nonadherence has been identified as a major health problem [34]. Decreasing the burden associated with CIC can increase patient acceptance of catheter use and thus increase compliance with the recommended number of catheterizations per day [35]. In patients with spinal cord injury dissatisfaction with CIC decreases about 5% per year since injury, and patients who are not able to establish a routine are more likely to move on to a different management strategy soon after injury [36]. A study preformed in United States established that only 50% of spinal cord injured adults use intermittent cath-

eterization after the initial injury, and usage declines over time with as high as a 50% drop-out rate at 5 years [37]. Negative feelings and experiences from the past may lead to low motivation. Patients may view CIC as a task they must perform, rather than a technique that brings choice and freedom in resolving urinary problems [38]. Patients perceive the combination of CIC and active social life as difficult and they seem to choose between avoiding activities or not compliance with the prescribed CIC frequency [39]. It was found that children using Mitrofanoff catheterization were more adherent to treatment than children using urethral CIC [7]. Self-catheterization has advantages over assisted catheterization in terms of empowerment, privacy, and autonomy [40]. Understanding patients' preferences, needs, and opinions about specific catheters and catheter features is essential if the consequences of nonadherence are to be avoided [16]. No single catheter is the perfect solution for all the patients, and they should be offered more options according to their needs [35].

Patients want to perform catheterization as quickly as possible and do not want to lose time. Pre-lubricated catheters are less time-consuming and more convenient, particularly when used outside the home. They can be used immediately and do not need any lubrication procedure [41,42]. Pinder, *et al.* (2015) reported that convenience and ease of insertion are important to patients [43]. Koeter, *et al.* (2019) translated convenience in more specific features such as catheter's portability and the fact that are ready to use and these two were considered as important catheter features [16]. The overall satisfaction with the hydrophilic-coated catheter is higher than satisfaction with the uncoated catheter [1,12,16]. In both hydrophilic and uncoated catheters show the lowest satisfaction on parameter "preparation of catheter outside usual surroundings" [12]. Catheter reuse increases the risk of CIC-related complications, which affects the acceptance of intermittent catheterization. Single-use hydrophilic-coated catheters improve quality of life and are preferred over catheter reuse [11].

Even though the fear for potential urethral damage is present and justified in terms of catheter stiffness, male patients report that greater rigidity was important because of the faster insertion through the urethra [41]. Catheter insertion must be gentle and even though the stiff tube is easier to insert, patients should be warned of possible urethral injuries. The no-touch grip can make the insertion of the catheter easier. The no-touch method with insertion grip shorten the catheterization time and provides method for less sterility errors, which reduces the risk of contamination of the catheter and the risk of urinary tract infections in a hospital setting and in home care [44]. Patients acknowledged the use of the insertion grip on the hydrophilic coated catheter and was treated as a hygienic measure allowing no-touch catheterization and was experienced as important by 85% of users [16].

Even today, there is a level of taboo and stigma to urinary problems in society in general and this is the reason for the non-adherence of catheterization. Feeling of shame is commonly reported in patient performing CIC. Therefore, patients felt the need for secrecy and discretion, which sometimes complicated or prevented the performance of CIC [38,39]. Patient preferences in Chartier-Kastler, *et al.* (2013) study demonstrates that the benefits of the discreet design of catheter is important to patients [35]. Koeter, *et al.* (2019) concluded that 89% of patients found the slim catheter design appealing and 67% found the foldable feature of the catheter to be important [16].

Catheter characteristic in our practice

Urinary catheters are frequently used in our center in both pediatric and adult patients, for various indications. Recently, we have tested pre-hydrated hydrophilic coated catheter (LentisCath™, Lentismed, Croatia) in our practice, based on its good attributes. We have been using LentisCath hydrophilic urinary catheters in both pediatric and adult patients for clean intermittent catheterization, which is managed through urethra, or through catheterizable channels, such as Mitrofanoff continent urinary diversion. Hydrophilic urinary catheters are used in these cases every 6-8 hours to empty the bladder [45]. We have also used it intraoperatively, as well as a part of postoperative treatment where catheterisation is required (hypospadias, epispadias, urethral strictures). We have noticed many advantages in all cases, compared to previous catheters. Pre-hydrated hydrophilic coated catheter is a product packaged with the saline solution already coated on the catheter's tube. It can be lubricated immediately and has the advantage of being able to insert the catheter immediately after opening. LentisCath catheter tube is made of thermoplastic polyurethane elastomer and is less rigid compared to other PVC catheters. Therefore, LentisCath catheter allows gentle manipulation during catheter insertion so we can assume that the incidence of UTI and trauma

are reduced due to this factor. Atraumatic drainage eyes over which a hydrophilic layer is applied also contribute to gentle insertion. The osmolality of the hydrophilic coating is sufficient, we did not detect adhesions to the urethral wall and wall of catheterisable stoma or increased friction during removal of the catheter even with prolonged catheterization. Since the catheter contains water solution and it is ready to use after the opening of the packaging it eliminates the need for extra steps and time in process of catheterization. It puts accent to the security provided, in terms of reducing the possibility for contamination of catheter with bacteria by minimizing preparation steps for catheterization. This is also a very handy benefit to users with neurological disorders and ones with impaired fine motoric.

We have achieved very good results so far with hydrophilic catheters, without signs of injuries of the (neo)urethra or catheterisable stoma. All patients reported satisfaction, as catheters are easy to use and cause very low rate of bladder and urethral irritation, as well as urinary tract infection. There were no cases of febrile ITU, as well as urethral bleeding or urethral stricture. Additionally, parents have reported on ease of use in children who need CIC in correlation to no-touch grip which reduces the risk of urinary tract infections. Packaging of the catheter is made of aluminium which is very durable, and secure of leakage, which our users find being an important benefit. In case of clean intermittent catheterization, design is very practical to fit every social situation keeping user's discretion.

Finally, it is also worth noting that users are becoming increasingly aware of environmental concerns and are therefore reporting additional concerns about the amount of waste produced by disposable catheters. The use of biodegradable materials, such as thermoplastic polyurethane, in catheter tubes and recyclable packaging, such as alumni, responds well to their concerns.

Despite the obvious drawback of short-term follow-up, our initial experience indicates good clinical results in using this pre-hydrated hydrophilic coated catheter with high rate of patients' satisfaction, which confirms its excellent characteristics. Further investigations and well-design studies are necessary for definite conclusions.

Conclusion

Patients in our clinical practice reported a high level of satisfaction and adherence to the evaluated LentisCath hydrophilic-coated catheter, enabling no-touch catheterization in both urethral intermittent catheterization and through catheterizable channels, such as Mitrofanoff continent urinary diversion. Due to insufficient evidence in the available studies, no firm guidelines can be established, however, based on the available data, catheters with a hydrophilic coating that are ready to use, soft catheter tube, atraumatic drainage eyes and no-touch grip, will reduce the risk of complications associated with clean intermittent catheterization. LentisCath catheter is safe to use with high patient adherence.

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Volume 3 Issue 2 February 2021

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