Korean J Neurotrauma. 2019 Oct;15(2):77-87
https://doi.org/10.13004/kjnt.2019.15.e41
pISSN 2234-8999·eISSN 2288-2243

KJNT

Review Article

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Recent Updates in Urinary Catheter Products for the Neurogenic Bladder Patients with Spinal Cord Injury

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OPEN ACCESS

Received: Oct 3, 2019
Revised: Oct 13, 2019
Accepted: Oct 14, 2019

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Conflict of Interest
The authors have no financial conflicts of interest.

ABSTRACT

Clean intermittent catheterization (CIC) is one of the core elements of neurogenic bladder management in the patients with spinal cord injury and is effective and safe to maintain low intra-bladder pressure and achieve urinary continence. Until now, the most notable development in urinary catheter products for CIC is the introduction of hydrophilic coating. Fortunately, in Korea, the national medical insurance has recently covered the cost for urinary catheters in this patient group. The purpose of this review is to summarize the history of CIC and the recent development of urinary catheter products. From our review, we would like to suggest a way of thinking that is the way forward for the future to improve the implementation of CIC with minimal morbidity.

Keywords: Clean intermittent catheterization; Neurogenic bladder; Spinal cord injury; Urinary catheter

INTRODUCTION

In patients with spinal cord injury (SCI), the ultimate goal of neurogenic bladder (NB) management is to maintain low intra-bladder pressure during the filling phase in order to prevent upper urinary tract damage and to achieve urinary continence by adequately draining urine. The mean age at the time of SCI is 30.7 years,[6] and when it is assumed that the patient sustained damage at the age of 40, the remaining life expectancy of a quadriplegic patient with C1-4 level injury is assumed to be about 22.1 years.[27] Therefore, this patient group should receive long-term follow-up for NB throughout their lives.

Depending on the spinal cord area involved, conus medullaris or cauda equina involvement leads to the development of acontractile detrusor, and in the patients with supra-sacral injury, neurogenic detrusor overactivity and detrusor-sphincter dyssynergia (DSD) mainly occur. In addition, in the cases of SCI above the T5/6 level, the possibility of autonomic dysreflexia occurring, which may lead to a medical emergency for the patients, should always be kept in mind during urological examination. Depending on the severity, detrusor compliance

decreases caused by injury at conus medullaris or cauda equina, or DSD from supra-sacral SCI, are all the elements negatively affecting the function of upper urinary tract.[13]

International Consultant on Incontinence concluded that intermittent catheterization (IC) is an effective and safe method in the short and long-term for the management of NB.[41] However, as long-term use may increase adverse events in the bladder and urethra, it is recommended that appropriate catheter materials and catheterization techniques should be well educated and implemented.[41] Several studies to date have reported the usefulness of various techniques and catheter materials for IC, and the most notable development in catheter-related products so far is the hydrophilic coating. Fortunately, in Korea, the national medical insurance has recently covered the cost for urinary catheters in this patient group.

The purpose of this review is to summarize the history of clean IC (CIC), one of the core elements of NB management in the patients with SCI, and the recent development of urinary catheter products. From our review, we would like to suggest a way of thinking that is the way forward for the future to improve the implementation of CIC with minimal morbidity.

HISTORY OF URINARY CATHETERIZATION

Urinary catheterization is one of the first treatments in human history, which has been practiced since ancient times. In ancient China, there were records of the use of onion stalks, and in 1000 BC, there were records of urinary catheter made of gold, silver, iron, and wood. In the West, Hippocrates (460–377 BC) used urinary catheter to treat bladder stones, and urinary catheters made of copper were found in the excavation of Pompeii, which was buried in a volcano in 79 BC. And then, Rhazes (865–925) described the urinary catheter with side-hole, and urinary catheter was further developed with industrialization. In 1844, Charles Goodyear introduced the rigid rubber catheter, and in 1860 Auguste Nelaton introduced the flexible rubber catheter. At the same time, Charriere developed a sizing system known as the French scale. By the late nineteenth century, many urinary catheters had already been developed and over 80 different kinds of catheters were described.

After Frederick Foley introduced the indwelling rubber balloon catheter in 1935, the urinary catheter became more widely used, and in 1946 Guttmann suggested that sterile IC was more desirable than maintaining the catheter for a long time. Later, in 1970, Jack Lapides introduced CIC for the first time in a 30-year-old female patient with multiple sclerosis and now CIC is established as the standard management for urinary drainage in the SCI patients with NB.[4]

Lapides et al.[18] asserted that the most important way to reduce the rate of urinary tract infection (UTI) is to improve bladder blood flow by reducing the pressure in the bladder with IC, rather than apply the sterile technique. In their study, they reported that the clean technique did not differ from the sterile technique in terms of renal impairment and UTIs. Since then, the clean technique has been continuously validated against the sterile technique. Duffy et al.[9] found that the both techniques had no significant difference in the occurrence of symptomatic UTI and that the clean technique was more advantageous in terms of cost. King et al.[15] also compared sterile single-use catheter and clean multiple-use catheter, indicating no significant difference in the occurrence of symptomatic UTI. Recently, Moore et al.[23] reported no significant difference in the incidence of symptomatic UTI between the

https://doi.org/10.13004/kjnt.2019.15.e41

both methods, and reported that the clean technique has cost and time benefits. The sterile technique is primarily recommended for hospitalization at the early stage of the disease, with the possibility of nosocomial infection, but is not recommended afterward since the clean technique is safe in most daily routines, and long-term prophylactic antibiotics can cause bacterial resistance and is not recommended.

ADVANTAGES AND DISADVANTAGES OF CIC AND PATIENT EDUCATION

In summary, the benefits of CIC are that it can maintain renal function by reducing the pressure in the bladder, make the bladder mucosa more safe against pathogen invasion by improving bladder blood flow, and minimize bladder degeneration due to chronic urinary retention. In addition, by achieving urinary continence, the patient's quality of life can be improved. Another important advantage of CIC is that it allows the patient to understand the course of the disease and participate in the course of management. However, the disadvantages of CIC should also be considered. In daily activities, a patient should carry a catheter when he or she goes out, may need a suitable place to conduct CIC and tap water. The procedure itself can damage the urethral mucosa and cause associated UTI or urinary tract deformity.[33,41]

When educating on CIC, the patient or guardian should be fully informed of the purpose of implementation of CIC as described above and explained on the different catheter types, and the most appropriate catheter type for the individual patient. Patients with social life may use different types of catheter at home and at work. In general, when voiding is not possible at all, CIC is usually performed 4–5 times a day. If voiding is possible but a large amount of post-void residual (PVR) remains, the frequency of CIC is determined according to the amount of PVR.[26] For the amount of PVR of 300 mL or less, 1–2 CICs are performed a day. The education includes teaching on the anatomical structure of the urethra, preparation and maintenance of hygiene before catheter insertion, and practical training of CIC. If a reusable catheter is utilized, training should also be given to disinfection and maintenance of the catheter.[33,34]

In implementing CIC, one of the patient's concerns would be urethral mucosal damage and UTI due to CIC. However, many of the studies to date have not shown significant adverse events and reported that CIC is problematic only in some of the male patients. Hematuria and urethral stricture occur in 1–2% and epididymitis in 2–9%, and these adverse events are commonly observed in patients with neurological abnormalities, mainly urinary regurgitation into the ejaculatory duct.[28] Urethral discomfort occurs during CIC in 10–15% and it usually arises when the catheter is taken out from the urethra.[25,40] Reports in urethral mucosal bleeding due to urethral mucosal damage are relatively common, and Webb et al.[40] studied 163 patients and urinary mucosal bleeding occurred in 74% during implementing CIC and persistent mucosal bleeding occurred in 28% after 3 months. Asymptomatic bacteriuria is frequently observed, with the proportion of sterile urine reported in 14–66% and 49–62% in the sterile technique in several reports.[11,17] Asymptomatic bacteriuria, in general, requires no treatment, and Mohler et al.[22] reported no significant difference in the incidence of symptomatic UTI when treating or observing asymptomatic bacteriuria. However, antibiotic therapy may be recommended for symptomatic persistent bacteriuria or recurrent UTIs.[28] The incidence of symptomatic UTIs has been reported to be once per 14 patient-months,[28] or 43% in 3.7 years of follow-up.[21] To prevent UTI, a urethral introducer has been developed

https://doi.org/10.13004/kjnt.2019.15.e41

that bypasses bacterial colonization in the distal urethra of 1.5 cm, significantly reducing the incidence of UTI in patients with SCI.[2] CIC procedure may induce some symptomatic UTI. Nevertheless, it is important to explain to patients that more symptomatic UTIs occur by not performing CIC. In addition, a recent report found that performing CICs was mostly easy, less painful, and not disruptive in daily life, and the quality of life was improved in more than 60% of patients.[14] In this regard, it should be explained to patients that in the long-term, performing CIC will be beneficial rather than burdensome.

There is no conclusion on whether single-use or multiple-use is superior in the CIC catheters. King et al.[15] compared the sterile single-use catheter and the clean multiple-use catheter with no significant difference in the occurrence of symptomatic UTI. Schlager et al.[35] reported no significant difference in incidence of bacteriuria related with CIC when they compared sterile single-use catheter and clean multiple-use catheter in pediatric patients. Recently, however, Vapnek et al.[38] compared the single-use hydrophilic coating catheter (LoFric®) with the multiple-use conventional plastic catheter, and found that urethra mucosal damage and occurrence of UTI were significantly lower in the single-use hydrophilic coating catheter group. However, this type of research has differences, strictly speaking, not only in the matter of reuse, but also in terms of hydrophilic coating from the previous studies, so these differences can be problematic in interpreting the results. In the study by Moore et al.,[24] which analyzed 4 small-scale studies, there was no difference in the incidence of symptomatic UTI with catheter reuse. Kovindha et al.[16] did not compare it with a single-use catheter, but emphasized the importance of disinfecting the catheter during CIC because the multiple-use silicone catheter increases the risk of UTI.

There is no established standard for disinfection method for reusable catheter. Bogaert et al.[5] compared the microwave oven with 70% alcohol as the method of disinfecting the catheter. Microwave exhibited antimicrobial effect only in *Escherichia coli* out of 3 types of pathogens used in the experiment. On the other hand, 5-minutes disinfection with 70% alcohol showed antimicrobial effects on all 3 pathogens. In addition, alcohol disinfection had no significant effect on the catheter material.

In clinical practice, CIC can be difficult to perform, depending on the patient's accompanying disability, in such cases, equipment such as hand grip, inflatable or metal adjustable leg divider with mirror, sheath expander, penis holder or stretcher, and labia separator can be used to assist CIC in the difficulties.

URINARY CATHETER MATERIALS AND THEIR DEVELOPMENT

As CIC became popular in the relevant patients, there have been many advances in the material of the catheter. Basically, CIC has many advantages in itself, but the material of the catheter may affect urinary deformity such as urethral mucosa damage, occurrence of UTI, and patient discomfort. Urethral catheter materials include rubber, silicone, and plastic (polyvinyl chloride [PVC], polyether block amide [PEBA], etc., **FIGURE 1**). There have been few studies comparing materials thru randomized fashion. However, as a result of the development of hydrophilic coating catheter, the comparison with the existing uncoated catheter has been made, and studies to compare different types of hydrophilic coating catheter have been reported.

https://doi.org/10.13004/kjnt.2019.15.e41

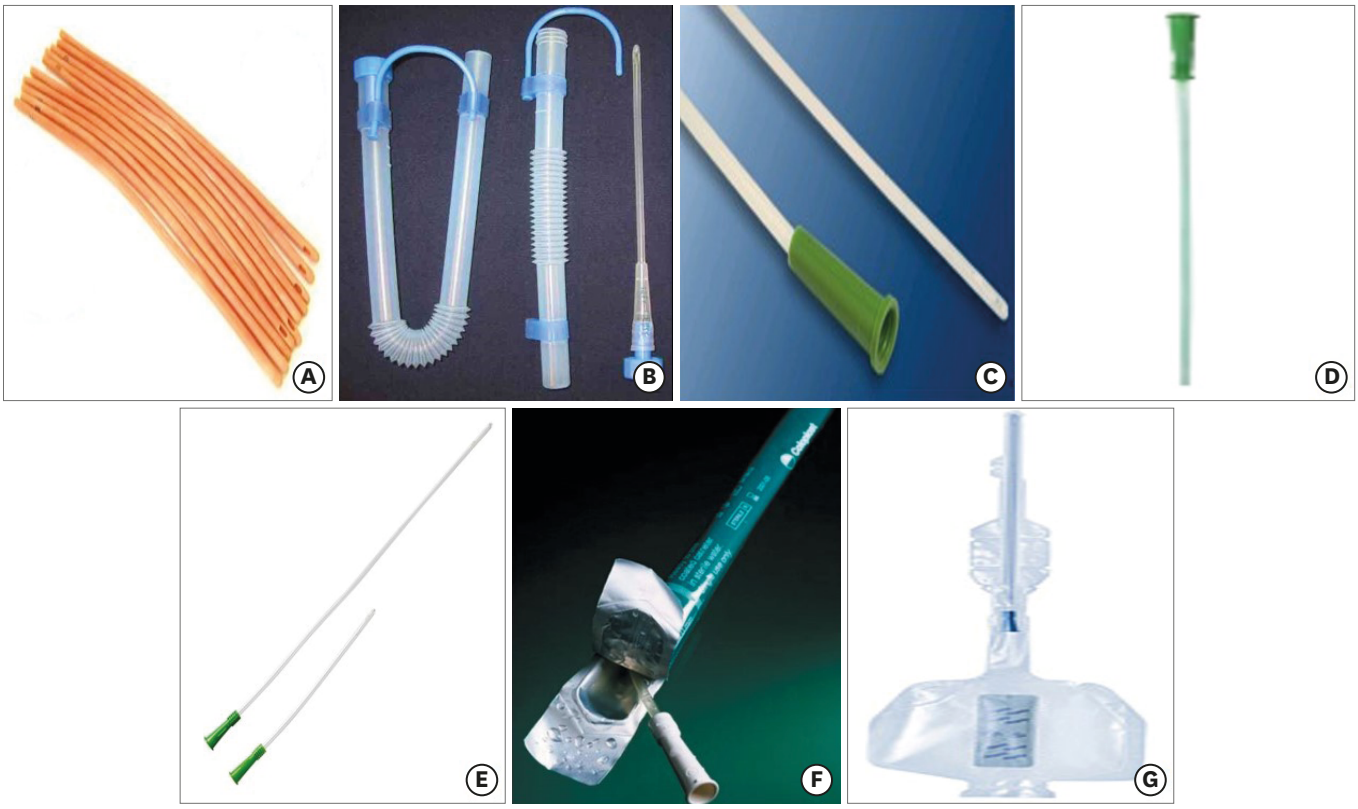

FIGURE 1. The urinary catheters made of various materials for clean intermittent catheterization. (A) Rubber catheter (the Nelaton catheter). (B) Silicone reusable catheter. (C) Plastic-polyvinyl chloride catheter. (D) Plastic-polyether block amide catheter. (E) Hydrophilic coating plastic catheter. (F) Pre-hydrated hydrophilic coating polyurethane catheter. (G) Self-contained system catheter.

Rubber catheter

Rubber has been used since the early days as a urinary catheter. It is commonly known as the Nelaton catheter, after its inventor, the French surgeon Auguste Nelaton (1807–1873). It is the most flexible among the various catheter materials, but it may be difficult for the elderly, etc., to be inserted into the urethral meatus. The length is usually 32cm, the thickness of the number 1 is 1.5 mm in diameter, and each time the number is increased, the diameter increases by 0.5 mm (**FIGURE 1A**). As it is inexpensive and reusable, it is one of the most commonly used materials in Korea. It cannot be used if the patient is allergic to Latex, etc.

Silicone catheter

Silicone is a synthetic rubber, one of the most biocompatible materials available today, with low tissue toxicity and inflammatory response. It is resistant to water and maintains its properties at high temperatures. Like PEBA materials, it is strong against chemicals and is disposable or reusable. Portable kits have been developed and widely used in Korea (Cliny®), and 0.5% chlorhexidine disinfection is used for the kit (**FIGURE 1B**). In addition, long-term reuse is possible. Kovindha et al.[16] studied the safety of reusable silicone catheters. The catheters used for 2 years had encrustation, but the lumen was not blocked and stiffness increased by about 20%. In addition, there was no difference in urethral deformation due to CIC in reuse or disposable catheter. However, although not compared with disposable catheters, reusable silicone catheters may increase the risk of UTIs.

https://doi.org/10.13004/kjnt.2019.15.e41

Plastic catheter

PVC catheter

PVC is relatively inexpensive and has a large inner diameter, which is advantageous for the drainage of urine (**FIGURE 1C**). Although the material is somewhat stiff, the patient may feel uncomfortable, but some products are somewhat soft.[29] This material is used all over the world, but some patients are allergic. Depending on the hydrophilic coating, it can be divided into 2 types. PVC nelaton without hydrophilic coating is generally reused and used for about 1 week.

PEBA catheter

PEBA is an environmentally friendly material and is PVC-free plastic. It is durable and flexible but maintains some strength. Also, it is resistant to chemicals and more biocompatible than PVC.[30] PEBA catheter (LoFric-Plus®) is softer and pliable than PVC and may be suitable for patients who are familiar with red rubber catheter (**FIGURE 1D**).

Hydrophilic coating

Various methods are used to reduce the friction between the surface of catheter and urethral mucosa. Simply lubricating gel is used every time inserting the catheter, but products with hydrophilic coating or gel coating on the surface of catheter itself can easily reduce friction without jelly.

Gel-coated pre-lubricated PVC or silicone catheter has been introduced, and Giannantoni et al.[10] compared conventional nelaton with pre-lubricated non-hydrophilic catheter. Asymptomatic bacteriuria and UTI were less in pre-lubricated non-hydrophilic catheter and patient's satisfaction was also reported to be significantly higher in patients using this catheter. They compared urethral mucosa damage by the number of urothelial cells attached to the surface of the catheter, and also less damage was reported in pre-lubricated non-hydrophilic catheter.[10]

Recently, hydrophilic coating catheter is a subject of many studies and also commercially available. This catheter typically uses PVC material and for coating materials, polyvinylpyrrolidone (PVP) and sodium chloride (NaCl) crystal are used (**FIGURE 1E**). PVP is a nonreactive hydrophilic polymer that absorbs water close to 10 times its weight when in contact with water. NaCl crystals act to enhance water-binding ability by increasing osmolality. Lubrication is performed by soaking in tap water or saline for 30 seconds before use. PVP chain binds to lubricating liquid, which binds with osmolality similar to that of urethral epithelium. Therefore, the contact area between the surface of the catheter and the urethral mucosa forms an area composed mostly of water molecules, so the friction between the catheter and the urethral mucosa is greatly reduced.[19,39]

Lundgren et al.[20] reported in animal studies that osmolality of hydrophilic coating catheter is important in reducing catheter friction in the urethra and preventing mucosal damage. Theoretically, the longer the drainage time, i.e. the longer the catheter is located within the urethral lumen, the lower the friction if the higher osmolality of the coating is maintained. Waller et al.[39] compared 2 different hydrophilic coating catheters in a cross-over study, and found that catheter with high osmolality (approximately 900 mOsm/kg) had significantly lower coefficient of friction when catheter was removed. In a comparative study with conventional catheter, Diokno et al.[8] and Sutherland et al.[37] reported that the frictional force of hydrophilic coated PVC catheter (LoFric®) was 5–10 times lower than that of the

https://doi.org/10.13004/kjnt.2019.15.e41

catheter lubricated with chlorhexidine jelly. Commercially available products include LoFric®, EasiCath®, and SpeediCath®.

For the advantages of hydrophilic coating catheter, it can be expected that less frictional force results in less urethral mucosa damage and less patient discomfort. In addition, this may reduce the incidence of UTI. Several studies have reported that hydrophilic coating catheter may reduce the risk of urethral mucosal damage,[1] facilitate insertion of catheter,[32] lower long-term adverse events such as bacteriuria and urethral stricture.[12] Sutherland et al.[37] compared LoFric® catheter and conventional PVC catheter in 32 patients, and urethral mucosa damage was significantly lower in LoFric® catheter group, but there was no statistically significant difference in bacteriuria incidence in both groups. Wyndaele et al.[43] reported that when hydrophilic coating catheter was used in patients who had used conventional catheter, the hydrophilic coating catheter was easier to use, and especially showed higher satisfaction among patients who had difficulty using conventional catheter. However, some patients were not satisfied in the actual clinical use or economic aspects.

Stensballe et al.[36] investigated the friction of hydrophilic coating catheter in healthy male adults. The hydrophilic coating catheter (SpeediCath®, LoFric®) and the uncoated gel-lubricated catheter (InCare® Advance Plus) were compared. In 93% of the subjects, the hydrophilic coating catheter was preferred and the hydrophilic coating catheter had significantly less hematuria, which led to less incidence of urethral mucosa damage. However, among the same hydrophilic coating catheters, SpeediCath® had significantly less friction than uncoated catheters and LoFric®, but LoFric® had significantly higher friction than uncoated catheters, which posed a question on the general concept that hydrophilic coatings themselves had less friction. In other words, friction and hematuria were not correlated, and perhaps it is thought that frictional forces were thought to cause urethral damage in different ways. Increasing the frictional force is thought to increase the irritation of urethral mucosa, eventually causing inflammation and long-term complications.

In interpreting previous studies results on hydrophilic coating catheters, it is thought that although the reuse of catheters may always be a bias in the uncoated catheter group, but in sum, hydrophilic coating catheters may reduce urethral mucosa damage and reduce patient discomfort. However, further research is needed to investigate whether it reduces bacteriuria and symptomatic UTI. Recently, the domestic health insurance has covered the cost for CIC catheters in SCI patients with NB. Therefore, more relevant patients can enjoy a share in its advantage of the use of hydrophilic coating catheter under the national insurance system. The use of hydrophilic coating catheter in clinical practice is thought to be appropriate for patients who experienced some discomfort or difficulty or those with frequent urethral mucosa damage such as hematuria when CIC was performed with the conventional uncoated catheters.

Recently, a pre-hydrated hydrophilic coating catheter (SpeediCath®) has been developed, which is a product packaged with the saline already coated on the coating catheter, can be lubricated immediately and has the advantage of being able to insert the catheter immediately after opening (**FIGURE 1F**). In other words, it is not necessary to obtain tap water or saline for lubrication, and may be more useful when there is some limitation of dexterity. SpeediCath® is made of polyurethane, and in the coating method, it is chemically adhered to the surface and, unlike the conventional method, the coating pattern is more consistent and well maintained. In Western reports, Pascoe and Clovis[32] reported that SpeediCath® had a faster

https://doi.org/10.13004/kjnt.2019.15.e41

CIC time than conventional coated catheters in 76% of patients. De Ridder et al.[7] compared the pre-hydrated hydrophilic coating catheter (SpeediCath®) and the uncoated PVC catheter for 1 year, and the results showed that there was a difference in UTI rate with 64% vs. 82%, respectively, and patients also showed higher preference for pre-hydrated hydrophilic coating catheter. However, the incidence of hematuria, pyuria and bacteriuria showed no difference between the both catheters.

Self-contained system (no touch technique)

Recently, a kit has been developed in which a sterile saline and a urine collecting bag are pre-packed with a coating catheter (**FIGURE 1G**). Typically, the sterile saline that is already in the urine bag is used for lubrication for 30 seconds and the special guide mechanism is used to insert the catheter into the urethral meatus. Therefore, the catheter is not directly touched during CIC. In other words, it can be expected to reduce the risk of UTI. Commercially available products include the SureCath™ set and LoFric Hydro-Kit II. LoFric® Primo™, which is similar to a self-contained system, also requires no tap water and the catheter is not directly touched with a special guide mechanism. In one study,[3] 74% of patients who have been using the standard PVC catheter were willing to switch to LoFric® Primo™. On the other hand, 36% of patients who have been using coating PVC were willing to change the product.

CONCLUSION

The goal of NB management for SCI is to maintain low intra-bladder pressure to prevent upper urinary tract damage and to achieve urinary continence. In 2005, International Consultant on Incontinence concluded that IC is an effective and safe method in the short- and long-term.[42] However, as long-term use may increase adverse events in the bladder and urethra, it is recommended that appropriate catheter materials and catheterization techniques should be well educated and implemented.[42] Several studies to date do not give clear conclusions on which method is better, depending on the technique (sterile or clean), presence of hydrophilic coating, or reuse. Therefore, the technique and the catheter material to be used are determined clinically, and the opinion of the patient is also important. In addition, depending on the medical insurance coverage level in each country, economic aspects such as the price of the catheter will be one of the factors affecting the choice. Well-designed large-scale randomized studies should be conducted to further investigate whether these improving catheter-related factors are meaningful in actual clinical practice.

The most notable development in catheter-related products so far is the hydrophilic coating. Fortunately, in Korea, the national insurance has recently covered the cost for CIC catheters in SCI patients with NB. In several small-scale studies, hydrophilic coating catheter is thought to reduce the discomfort and urethral mucosa damage to some extent. Therefore, such hydrophilic coating catheter may be useful if at least existing catheter is difficult to insert into the urethra, if the patient experienced urethral damage, or frequent recurrence of UTI. In addition, we also should consider the proper method for CIC education in the clinical setting. Oh et al.[31] evaluated the effects of a centralized intensive education system in terms of acquiring a proper CIC technique. They prospectively enrolled 132 hospitalized patients who learnt and started CIC for the first time due to voiding dysfunction. Compared to individualized ward education system, the centralized intensive education system was more favored regarding patient satisfaction with CIC education and the number of trials to gain confidence to perform CIC. Therefore, for the method for CIC education, centralized

https://doi.org/10.13004/kjnt.2019.15.e41

intensive education system seems to be a superior training program to acquire a proper CIC technique for the patients with NB. We should fully educate the patient about CIC and follow up on it for proper performance.

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