Safety and Pain-relief Efficacy of Urethral Catheter with Local-anesthetic Injection Port

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Objectives : The NMOC 3-Way Catheter® (NMOC) functions as a conventional urethral catheter, but has a lumen for injection of local anesthetics. Available in Japan, the NMOC is reported to alleviate catheter-associated postoperative discomfort and pain at the time of catheter withdrawal. We investigated the safety and efficacy of pain reduction of the NMOC compared with a conventional urinary catheter during high-dose-rate brachytherapy (HDRB) of the prostate.

Methods : The NMOC (16 Fr, 10-ml cuff) was placed in 20 patients undergoing HDRB (NMOC group) ; 10 ml of 4% lidocaine was administered to the urethra through the injection port. A conventional catheter (16 Fr, 10-ml cuff) was placed in 10 additional HDRB patients (control group). Patients assessed their pain with a numerical rating scale (NRS) and face scale (FS). Higher scores indicated greater pain. The Mann-Whitney U test was used for statistical analysis ; $p<0.05$ was considered statistically significant.

Results : There were no differences in patient background between the control and NMOC groups. Pain scores were significantly lower in the NMOC group than in the control group both at the time of catheter exchange and during catheter manipulation. The frequency of analgesia use through the following morning did not decrease with NMOC use. However, the median time before first use of analgesics for catheter traction-associated pain was about 2 hours longer with NMOC use than in the control group. Median pain scores at the time of drug injection were 0 according to both NRS and FS. No complications occurred with NMOC use.

Conclusion : The NMOC was safely used in patients after HDRB of the prostate, and effectively reduced pain during catheter exchange and catheter manipulation better than a conventional urethral catheter. *Shinshu Med J 65 : 355—359, 2017*

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Key words : urethral catheter, local anesthesia, 3-way catheter, urethral pain, high-dose-rate brachytherapy

Abbreviations : Catheter, urethral catheter ; NMOC, NMOC 3-Way Catheter® ; HDRB, high-dose-rate brachytherapy ; NRS, Numerical Rating Scale ; FS, Face Scale

I Introduction

Indwelling urethral catheters are one of the most frequently used medical devices in urology. However, catheter manipulation causes pain, especially in males. To date there has been no effective pain-reducing strategy for patients with catheters, except for symptomatic therapy that depends on analgesics.

In Japan, a newly developed catheter with a lumen for injection of local anesthetic (NMOC 3-Way Catheter®) has been reported to be useful in alleviating postoperative catheter-related discomfort and pain at the time of catheter withdrawal. However, because the NMOC 3-Way Catheter® (NMOC) is not indicated for patients after urinary system surgeries, it is not currently used in these patients. According-

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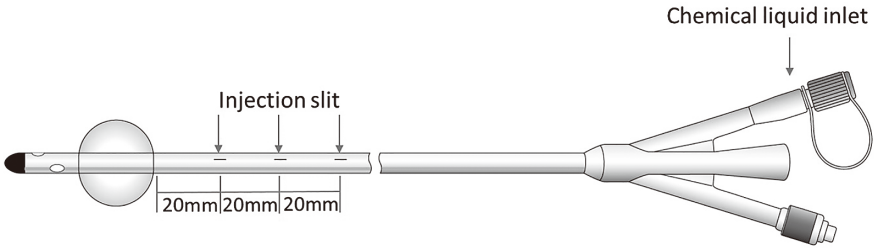

Fig. 1 Structure of NMOC 3-Way Catheter® (Modified from the package insert for NMOC)

Appendix 1 Questionnaire for evaluating pain during HDRB

※ Please include strong urinary sensation to pain	NRS (0–10)	FS (0–10)
1. What degree of pain did you have before this treatment?	NRS ( )	FS ( )
2. What degree of pain did you have during the afternoon irradiation?	NRS ( )	FS ( )
3. What degree of pain did you have when exchanging the balloon catheter?	NRS ( )	FS ( )
4. What degree of pain did you have during balloon catheter operation?	NRS ( )	FS ( )
5. Did you feel pain until early morning after balloon catheter traction?	YES	NO
What time did you feel the pain most strongly?	(around	:)
What degree of pain did you have at that time?	NRS ( )	FS ( )
Type of pain reliever, usage time : (nurse to fill in)		
Thank you for your cooperation.		

HDRB, high-dose-rate brachytherapy ; NRS, numerical rating scale ; FS, face scale

ly, we investigated the safety and efficacy of pain reduction of the NMOC compared with a conventional urinary catheter during high-dose-rate brachytherapy (HDRB) of the prostate, which affects the urethra and bladder and which can cause much pain during catheter manipulation.

Ⅱ Methods

In addition to ordinary catheter function, the NMOC is equipped with a lumen for injection of local anesthetics. **Fig. 1** shows the external appearance of the NMOC.

NMOC is designed with three slits positioned every 2 cm beginning at the distal end of the balloon. The local anesthetic solution exits through these three slits when injected through the drug injection port, making it possible to apply topical anesthesia directly to the urethral mucosa.

HDRB is performed under lumbar spinal anesthesia at our hospital. The first irradiation is performed after puncture of the prostate with an irradiation needle and the second is performed 8 hours later. Because no additional lumbar spinal anesthesia is added, the anesthesia wears off by the time of the second irradiation. After the second irradiation, the catheter is exchanged for an 18 Fr 3-way catheter for continuous bladder irrigation and to remove coagula from the bladder, after which catheter traction is applied until the next morning. Thirty patients underwent HDRB of the prostate from April to December 2016 at our hospital. Ten of these patients underwent HDRB with a conventional 16 Fr silicone Foley catheter with a 10-ml cuff (control group). Patients assessed their pain with a questionnaire (**Appendix 1**). Pain at the time of removal of coagula from the bladder after catheter exchange and pain during catheter traction were regarded as pain during catheter manipulation. HDRB was performed in the remaining 20 patients with the NMOC (silicone Foley catheter, 16 Fr, 10-ml cuff). 10 ml of 4% lidocaine was injected through the NMOC port after completion of the second irradiation. The same pain questionnaire survey was conducted in these patients (NMOC group). An additional question on the pain felt at the time of drug injection was included in the NMOC group. Patients who had

Table 1 Questionnaire result

	Control group 10 cases NSR/FS (Median)	NMOC group 16 cases NSR/FS (Median)	P value (NSR/FS)
Age (years) (Median)	55-80 (70)	62-80 (68.5)	0.7702
Pain before treatment	0-1 (0)/0-1 (0)	0-0 (0)/0-0 (0)	0.2059/0.1824
Pain during second irradiation	0-4 (0)/0-3 (1)	0-2 (0)/0-3 (0)	0.1001/0.0583
Pain during drug injection	-	0-1.5 (0)/0-1 (0)	-
Pain during catheter replacement	2-9.5 (7)/1-5 (4)	0-10 (1.5)/0-5 (1)	0.0055*/0.0102*
Pain during catheter operation	1-8.5 (6.5)/1-5 (4)	0-8.5 (1.5)/0-4 (1)	0.0064*/0.0084*
Postoperative analgesic use frequency	5/10 (50%)	11/16 (68%)	0.3485
Number of postoperative analgesic uses	0-2 (0.5)	0-5 (1.5)	0.2062
Time to mutual first postoperative analgesic use	1h20min	3h30min	-

P<0.05. NRS, numerical rating scale ; FS, face scale ; NMOC, The NMOC 3-Way Catheter

difficulty completing the questionnaire as a result of restlessness after surgery and those who refused to complete the questionnaire after surgery were excluded. The safety and efficacy of the NMOC was investigated in the remaining 16 patients. A numerical rating scale (NRS) and face scale (FS) were used to assess pain. The Mann-Whitney U test was used for statistical analysis ; $p<0.05$ was considered statistically significant. The safety of the NMOC was also investigated. Approval was obtained from the ethics committee of our hospital (Approval No. 27, City Hospital Ethics Committee No. 0204) before this study began. Furthermore, the intent of this study was explained to the patients in writing and their informed consent was obtained.

Ⅲ Results

The patients in the control group were 55 to 80 years of age (median, 70 years) ; those in the NMOC group were 62 to 80 years of age (median, 68.5 years). The median pain scores before the start of treatment according to the NRS and FS were 0 and 0, respectively, in both the control and NMOC groups. The median pain scores during second irradiation were 0 (NRS) and 1 (FS) in the control group and 0 (NRS) and 0 (FS) in the NMOC group. The above result indicated no difference in patient background between the groups. The median pain scores at the time of catheter exchange were 7 (NRS) and 4 (FS) in the control group and 1.5 (NRS) and 1 (FS) in the NMOC group, indicating significantly less pain in the NMOC group than in the control group (NRS, $p = 0.0055$; FS, $p = 0.0102$). The median pain scores at the time of catheter manipulation were 6.5 (NRS) and 4 (FS) in the control group and 1.5 (NRS) and 1 (FS) in the NMOC group, also indicating significantly less pain in the NMOC group than in the control group (NRS, $p = 0.0064$; FS, $p = 0.0084$). Postoperative analgesic use frequency in the control group was 50% and in the NMOC group it was 68%. The median number of postoperative analgesic uses in the control group was 0.5 and in the NMOC group it was 1.5. The median time to mutual first postoperative analgesic use in the control group was 1 hour 20 min and in the NMOC group it was 3 hours 20 min. Although use of the NMOC did not decrease the frequency of painkiller use through the following morning, the median time before the first use of analgesics for pain associated with catheter traction was about 2 hours longer in the NMOC group than in the control group. The reported pain at the time of drug injection ranged from 0 to 1.5 (median value, 0) according to the NRS and from 0 to 1 (median value, 0) according to the FS (**Table 1**). Regarding complications, there was one case of urinary retention in the control group and one case of postoperative restlessness in the NMOC group.

Ⅳ Discussion

Indwelling urethral catheters are one of the most

frequently used medical devices in urology to drain urine from the bladder. The pain and discomfort associated with catheterization have been well described. However, because of a lack of effective measures, only symptomatic therapy has been available to treat this pain without taking aggressive measures. Several reports in anesthesiology have confirmed the usefulness of the NMOC, which has been newly developed in Japan. However, use of the NMOC is prohibited in patients after urinary system surgery and in those with a damaged urethra because it is assumed that these patients would suffer from side effects caused by local anesthetic injection. Therefore, in this study we used the NMOC after HDRB, which affects the urethra and bladder and which can cause much pain during catheter manipulation. No adverse events clearly attributable to use of the NMOC were observed, including allergic reactions to the local anesthetic. Thus, our findings suggest that NMOC can be safely used in patients after urological surgery as well. As to the efficacy of the NMOC, pain was significantly alleviated both at the time of catheter exchange and during catheter manipulation compared with a conventional urinary catheter. In the field of anesthesiology, the NMOC had been reported to be effective in alleviating the discomfort of balloon catheter after surgery and reducing the pain at the time of balloon removal after surgery. This study produced the same results, so, we consider the NMOC to be useful for relieving pain compared with a conventional urinary catheter.

However, the type, concentration and amount of local anesthetic to administer via the NMOC have not been established and no studies have reported clinical experience with the device. According to reports presented at the Association of Anesthesiology, many clinicians have used 10 ml of 2% lidocaine or 5 ml of 4% lidocaine with the NMOC. Lidocaine was used as the local anesthetic in this study based on reports of its use on the urethral mucosa during flexible cystoscopy. Goldfischer et al and Holmes et al reported that lidocaine gel effectively alleviated pain during flexible cystoscopy[1)2)]. Because 4% lidocaine is currently used at our hospital during outpatient flexible cystoscopy, we decided to use 4% lidocaine in this study.

Concerning its pharmacological mechanism of action, lidocaine blocks the sodium channel of nerve membranes to reversibly inhibit the conduction of action potentials in the nerve, blocking both sensory and motor nerves[3)]. Lidocaine does not effectively infiltrate tissues. Because the efferent nerves of the urethra are located deep in the urethral wall[4)], they are unlikely to be affected by topical lidocaine injection into the urethra. Accordingly, lidocaine is considered an appropriate local anesthetic to block the submucosal afferent nerves. Furthermore, lidocaine causes little irritation either with topical use or in infiltration anesthesia. Goldberd et al reported no irritation reactions after application of 8% lidocaine solution to the cornea of rabbits, which are more sensitive to the effects of lidocaine than humans[5)]. The pain score at the time of injection of 4% lidocaine in the present study was 0 to 1.5 (median value, 0) according to the NRS and 0 to 1 (median value, 0) according to the FS, indicating negligible or no pain associated with lidocaine administration. As to the volume, injections of 5 ml and 10 ml have been reported. Because the usage method clearly states that it is necessary to ensure that the local anesthetic flows from the catheter side of the external urethral orifice when injected through the NMOC, the larger volume of 10 ml was used in this study to ensure outflow. However, further investigation is necessary to evaluate the best type, concentration and volume of local anesthetic to use with the NMOC.

The pudendal nerve is an afferent nerve of the somatic system involved in the pain experienced at the time of catheter exchange and manipulation. The urethral mucosa and pudendal nerve at the urethral sphincter and the afferent branches of the pelvic visceral nerves are related to the vesical reflex. Barrington et al reported that urinary flow under application of a catheter or mechanical stimulation of the urethra excited the afferent nerves and promoted the vesical contraction reflex in anesthetized cats[6)7)]. A subsequent study by Jung et al supported the findings of Barrington et al[8)]. These reports

strongly suggest that the urethral afferent nerves play an important role in the micturition reflex. It may therefore be possible not only to suppress urethral pain and urethral sphincter pain but also to inhibit the vesical reflex, thereby improving tenesmus, by injecting lidocaine into the urethra through the NMOC. In the present study, the time until use of additional painkiller was longer by about 2 hours when the NMOC was used. The effective duration of local anesthesia is about 2 hours. Therefore, we assume that both local pain and also the vesical reflex were suppressed during these 2 hours. The results of this study suggest that repeated administration of local anesthetic via the NMOC at the onset of pain can inhibit the vesical reflex, help control the discomfort of postoperative catheterization and reduce the amount of postoperative analgesics needed.

V Conclusion

Although further investigation is necessary, our findings indicate that the NMOC can be safely used in patients after surgery of the urinary system and is effective in reducing the pain associated with urethral catheter exchange and urethral catheter manipulation compared with a conventional urinary catheter. The effective duration of lidocaine is about 2 hours, and we suggest that repeated administration of local anesthetic via the NMOC at the onset of pain can inhibit the vesical reflex, help control the discomfort of postoperative catheterization and reduce the amount of postoperative analgesics needed.

COI : The authors declare no conflict of interest.

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