Validity of a disposable catheter to drain urine overnight in neurogenic bladder

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able 1. Evaluation of bacterial influx before, after urine and catheter

	Check valve				No check valve			
Specimen	Urine before (cfu/ml)	Urine after (cfu/ml)	Catheter (cfu/ml)	Feces in the diaper	Urine before (cfu/ml)	Urine after (cfu/ml)	Catheter (cfu/ml)	Feces in the diaper
1	-	-	*E. raffinosus* 10^3	A	-	-	-	P
2	-	-	*Corynebacterium sp.* 10^4 *E. faecalis* 10^3	P	-	*E.coli* 10^3	-	A
3	-	*B. subtilis* 10^3 *Corynebacterium sp.* 10^3 S. aureus 10^3	-	P	-	*E.coli* 10^3	-	P
4	-	*E. coli* 10^3	*E. coli* 10^3 *E. raffinosus* 10^3 *S. hyicus* 10^3	A	*E. gallinarum* 10^7	*E. gallinarum* 10^7	*E. gallinarum* 10^7	A
5	-	*E. coli* 10^4 *S. cohnii* 10^3	*S. hyicus* 10^4	P	*E. coli* 10^4 *M. morganii* 10^7	*E. coli* 10^7 *M. morganii* 10^7 *S. aureus* 10^6	*M. morganii* 10^3 *S. hyicus* 10^4	P
6	-	-	-	P	-	*S. aureus* 10^6	*S. aureus* 10^4	P
7	-	*E. faecalis* 10^3	-	P	*A. lwoffi* 10^7 *E. faecalis* 10^4	*E. faecalis* 10^3	-	A
8	-	*E. gallinarum* 10^3	*E. gallinarum* 10^3 *S. haemolyticus* 10^3	P	*E. gallinarum* 10^3	*E. gallinarum* 10^4	*E. gallinarum* 10^3 *S. haemolyticus* 10^3	A

Abbreviations: cfu/ml (colony forming units/ml), A (absence), P (presence), *A. lwoffi* (*Acinetobacter lwoffi*), *B. subtilis* (*Bacillus subtilis*), *E. coli* (*Escherichia coli*), *E. faecalis* (*Enterococcus faecalis*), *E. gallinarum* (*Enterococcus gallinarum*), *E. raffinosus* (*Enterococcus raffinosus*), *M. morganii* (*Morganella morganii*), *S. aureus* (*Staphylococcus aureus*), *S. cohnii* (*Staphylococcus cohnii*), *S. haemolyticus* (*Staphylococcus haemolyticus*), *S. hyicus* (*Staphylococcus hyicus*)

Table 2. Urine output and residual urine volume by NBE catheter with or without a check valve

Specimen	Urine output (ml)		Residual urine (ml)	
	Check valve	No check valve	Check valve	No check valve
1	20	30	75	0
2	60	50	5	0
3	10	40	35	0
4	20	80	5	0
5	30	70	10	2
6	150	50	0	5
7	20	30	6	2
8	80	40	1	0.4

Abbreviation: NBE (nocturnal bladder emptying)

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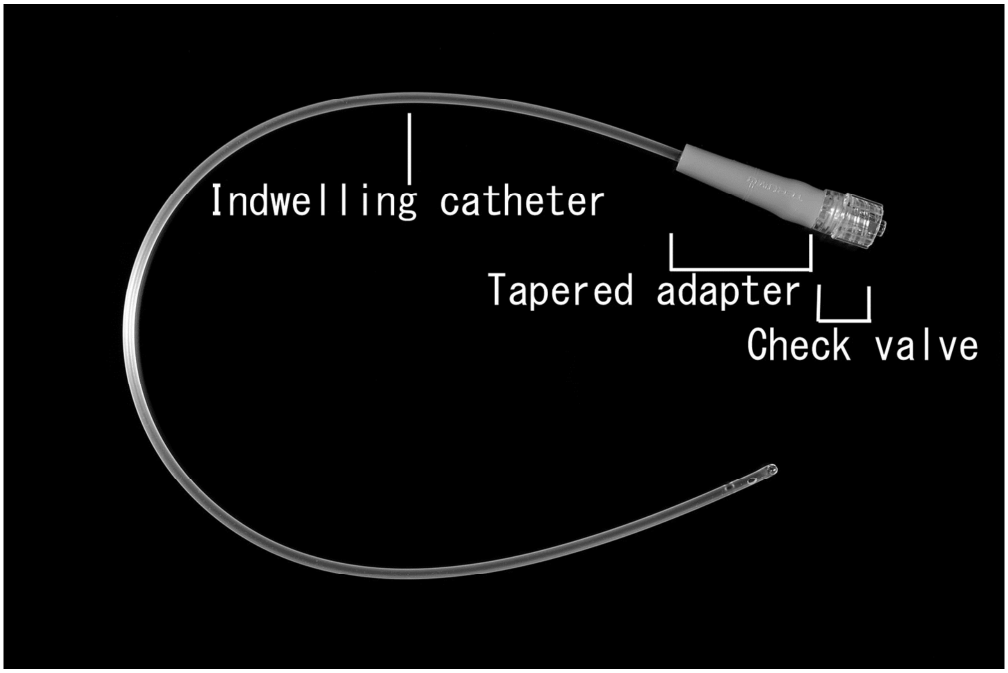

Figure 1: disposable silicon no-balloon (DSnB) catheter:
An 8-Fr indwelling catheter with a check valve for overnight catheter drainage (OCD)

150x99mm (300 x 300 DPI)

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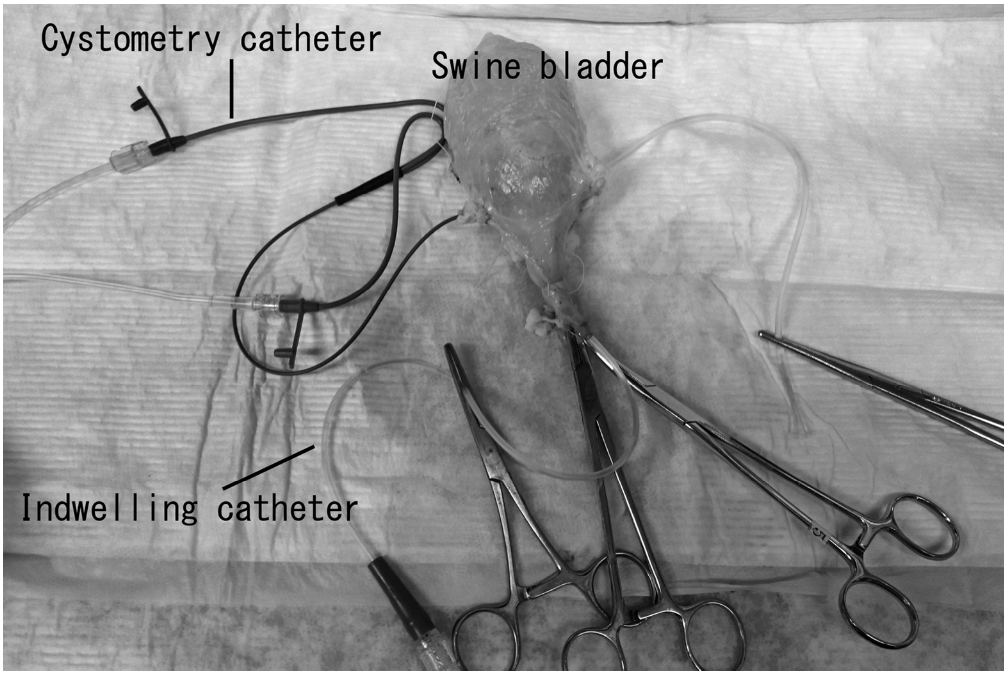


Figure 2: In vitro study
A cystometry catheter is inserted into the right ureter of a swine bladder and connected to a urodynamic testing system and a physiological saline reservoir. The left ureter has been ligated, and an indwelling catheter has been inserted into the urethra, which is closed with forceps to eliminate any gaps.

129x86mm (300 x 300 DPI)

view

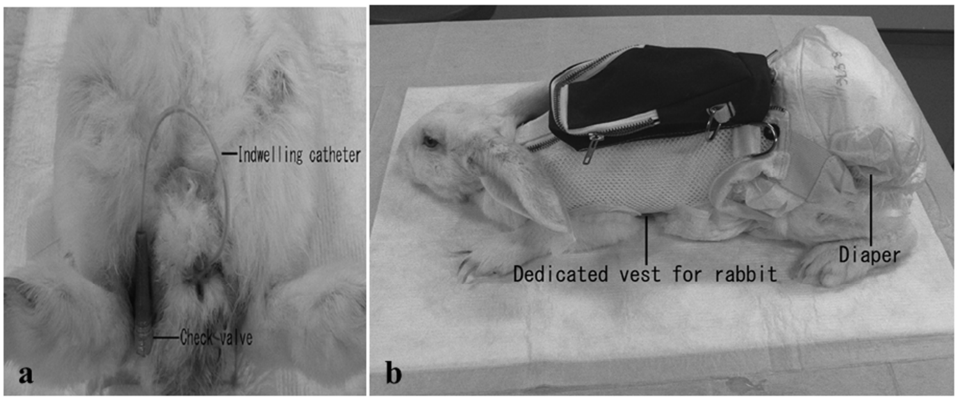
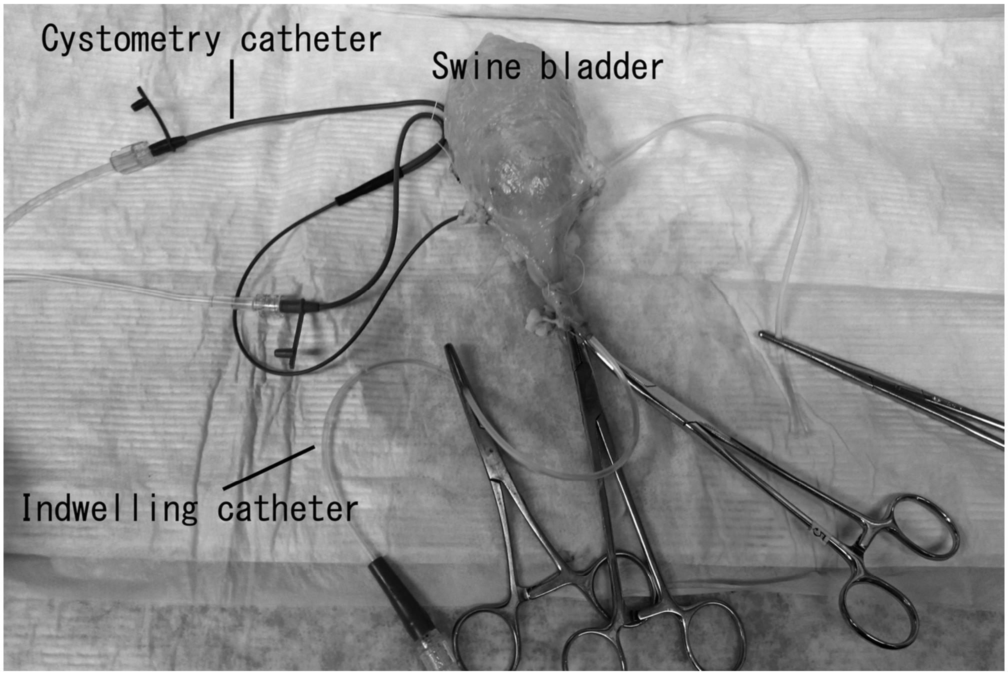


Figure 3: In vivo study
a: An indwelling catheter has been inserted into the bladder of a rabbit, after which the rabbit was fitted with an infant diaper into which the distal extracorporeal end of the catheter opened.
b: Each rabbit is fitted with a dedicated vest to prevent the diaper from falling off.

254x190mm (96 x 96 DPI)



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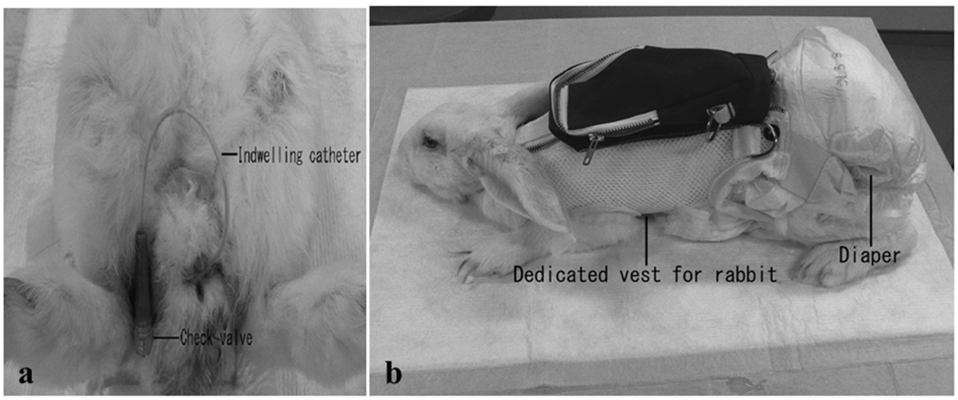

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Original article

Title: Validity of a disposable catheter to drain urine overnight in neurogenic bladder

Short running title: disposable no-balloon catheters for OCD

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ABSTRACT

Background: Overnight catheter drainage (OCD) is introduced to avoid overdistension of the bladder overnight when clean intermittent catheterization proves ineffective for daytime management of neurogenic bladder. We adopted OCD using disposable silicone no-balloon (DSnB) catheters, with the distal end outside the body opening into diapers, because catheters for infantile OCD are unavailable in Japan. This study examined the validity of equipping DSnB catheters with check valves to prevent retrograde bacterial contamination.

Methods: *In vitro*: Excised saline-filled swine bladders were drained using DSnB catheters with or without check valves, and the time required for intravesical pressure to reach 5 cmH_2O was measured. *In vivo*: In crossover experiments comparing DSnB catheters with and without check valves, OCD using DSnB catheters for 10 h was performed in rabbits under analgesia, opening externally into diapers. Bacterial growth from urine samples before and after OCD and residual urine volume were examined.

Results: *In vitro*: No significant difference in drainage time was seen between DSnB catheters with (n=6) and without (n=6) check valves (p=0.67). *In vivo*: In crossover experiments (n=8), new bacterial growth rates after OCD did not differ between catheters with and without a check valve. Median (range) residual urine volumes were 17.1 mL (range, 0–75 mL) and 1.2 mL (0–5 mL) with and without check valves, respectively (p=0.055).

Conclusions: Although OCD using DSnB catheters drained urine, installing a check valve in the DSnB catheter did not decrease new bacterial growth, while tending to increase residual urine volume.

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Key words: neurogenic bladder, disposable silicone no-balloon catheters, overnight catheter drainage, check valve, retrograde bacterial contamination

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Introduction

Clean intermittent catheterization (CIC) every 3–4 h during the daytime is used to avoid overdistention of the bladder, maintain low intravesical pressure, and reduce residual urine in patients with a neurogenic bladder due to spina bifida (1). In cases with progressive deterioration of the upper urinary tract and renal function despite optimal daytime CIC in patients, the efficacy of continuous urine drainage from the bladder using an indwelling catheter during the nighttime sleeping hours in addition to daytime CIC has been reported. Continuous urine drainage to avoid overdistention of the bladder during nighttime sleeping is known as nocturnal bladder emptying (NBE) (2, 3), continuous overnight catheter drainage (COCD) (4), or overnight catheter drainage (OCD) (5). Although reusable temporary indwelling balloon catheters for older children and adults are available (DIB International, Tokyo, Japan), no such catheters are available for infants in Japan. We therefore adopted a simple open drainage system using a disposable catheter for infantile patients, creating a situation similar to OCD (5) using an indwelling straight catheter. Specifically, a disposable silicone no-balloon (DSnB) catheter (Nelaton catheter with tapered adapter; Terumo, Tokyo, Japan) (Figure 1) was used for infantile OCD, with the distal end outside the body and opening into a diaper. Although the clinical efficacy of an open drainage system for OCD has been reported (5), such systems could risk backflow of urine including bacteria from feces or vaginal secretions in the diaper during sleeping time, and this issue has not been well examined.

We therefore devised a DSnB catheter equipped with a check valve to prevent retrograde infection. In this study, the validity of using a DSnB catheter with a check

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valve to prevention retrograde infection was examined *in vitro* and *in vivo* compared with a DSnB catheter without check valve, prior to clinical application.

METHODS

Both *in vitro* and *in vivo* experiments were conducted using DSnB catheters either with a check valve (Kawasumi check valve; Kawasumi Laboratories, Tokyo, Japan) or without a check valve. These experiments were approved by the animal experimental ethics committee at Iwate Medical University.

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1. Evaluation of intravesical pressure reduction (*in vitro*)

To examine whether use of a DSnB catheter with a check valve can impede reductions in intravesical pressure, bladders excised from swine (n=12) were divided into two groups for *in vitro* use. DSnB catheters with (n=6) and without (n=6) check valves were separately inserted via the urethra and clamped in each group.

For preparation, the DSnB catheter was inserted into the bladder via the urethra and sealed with two forceps to eliminate gaps around the DSnB catheter and avoid leakage. A cystometry double-lumen catheter (Urodynamic catheter; Coloplast, Tokyo, Japan) was inserted into the bladder via the right ureter and connected to a urodynamic testing system (Solar Silver; Medical Measurement System, Enschede, the Netherlands). To prevent pressure leakage, both ureters were ligated together with surrounding tissue using silk thread (Figure 2).

At the start of the experiment, saline was continuously infused into the bladder through the infusion site of the cystometry catheter until the intravesical pressure reached 20 cmH_2O. The forceps at the end of the DSnB catheter were removed, and the saline was allowed to drain from the bladder. Changes in intravesical pressure and time were continuously recorded until pressure reached 5 cmH_2O [3] or 20 min elapsed from the start of timing.

After this experiment, to examine whether a check valve effectively prevented backflow, the DSnB catheter was once again closed using forceps, and the bladder was filled with saline to an intravesical pressure of 20 cmH_2O. A negative pressure of 10 cmH_2O [3] was created by pulling on a syringe attached to the infusion site of the cystometry catheter. The distal end of the DSnB catheter was placed into a flask filled with saline stained with blue ink and reopened by removing the forceps, and the presence or absence of backflow into the DSnB catheter was examined.

2. Evaluation of bacterial influx (*in vivo*)

To examine differences in new bacterial growth and the volume of residual urine between DSnB catheters equipped with and without check valves *in vivo*, Japanese white male rabbits were used. Each rabbit was randomly assigned to the experiment using a DSnB catheter with or without a check valve. Rabbits (n=8) were weighed, then xylazine hydrochloride (4.0 mg/kg) and ketamine hydrochloride (50 mg/kg) were injected intramuscularly for analgesia and sedation [4]. DSnB catheters were then randomly inserted into the bladders via the genitalia, which were sterilized using chlorhexidine gluconate, to a 3-cm depth from the point at which outflow of urine occurred. The distal end of the DSnB catheter outside the body was fixed to the lower abdomen with elastic tape. Urine retained in bladders was aspirated using a syringe to empty the bladder and was used for bacterial culture testing. Rabbits were fitted with infant diapers and special vests (Rabbit jacket; Bio Research Center, Nagoya, Japan) to

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secure the diapers, after the distal end of the DSnB catheter outside the body was looped and opened into the diaper (Figure 3a, b).

Rabbits were returned to their breeding cages, with ad libitum access to food and water. After 10 h, residual urine was aspirated using a syringe, which was attached to the distal end of the DSnB catheter outside the body, measured and submitted for bacterial culture testing, after removing the vest and diaper. DSnB catheters were then removed, and the proximal end of the DSnB catheter was submitted for bacterial culture testing. Diapers were weighed again after removing feces to calculate the urinary output in 10 h.

This study was a crossover study wherein each rabbit was assigned to another experiment using a DSnB catheter either with or without a check valve, after a 1-week washout and recovery period.

New bacterial growth was defined as the appearance of new or other bacterial growth from aseptic and septic conditions, or enrichment of the same bacteria after 10 h of OCD.

Statistical analysis

In vitro: Comparisons of times between groups of DSnB catheters with and without check valves were analyzed using the Mann-Whitney U test.

In vivo: Frequencies of new bacterial growth in residual urine obtained from DSnB catheters with and without check valves in each rabbit were compared using Fisher's exact test. Moreover, differences in urine output and residual urine volume between DSnB catheters with and without check valves in each rabbit were compared using the Wilcoxon signed-rank test.

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All data in this article are shown as median (range), and the significance level was set at $p<0.05$ for the experiments.

RESULTS

1. Evaluation of intravesical pressure reduction (*in vitro*)

The lowest intravesical pressure after draining the bladder was 5 cmH_2O in both groups undergoing NBE using catheters with and without check valves. The time to reach lowest intravesical pressure (5 cmH_2O) did not differ significantly between groups, at 368.2 s (range, 88–1085 s) and 344.7 s (range, 28–840 s) in the groups having DSnB catheters with and without check valves, respectively (p=0.67).

When a negative pressure of 10 cmH_2O was applied using the syringe, no backflow was observed in any bladders in the DSnB catheters with a check valve group, whereas backflow was observed in all bladders in the DSnB catheters without a check valve group.

2. Evaluation of bacterial influx (*in vivo*)

Eight rabbits, weighing 3.59 kg (range, 3.30–3.85 kg), were used for the crossover experiments. New bacterial growth in urine after OCD for 10 h was observed in five each of the eight cases using NBE catheters with check valves (specimens 3,4,5,7,8) and without check valves (specimens 2,3,5,6,8), respectively. No significant difference was apparent (p=1.000; Table 1). Urine output for 10 h was 48.8 mL (range, 10–150 mL) and 48.8 mL (range, 30–80 mL), and residual urine volume was 17.1 mL (range, 0–75 mL) and 1.2 mL (range, 0–5 mL), in the eight cases having DSnB catheters with and without check valves, respectively. Although no significant differences in urine output

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were identified, residual urine volume tended to be greater in cases using DSnB catheters with check valves than in those without check valves (p=0.055; Table 2).

DISCUSSION

This study showed that urine drained from bladders and a low intravesical pressure was maintained using a simple open drainage system with a DSnB catheter, regardless of the presence or absence of a check valve *in vitro*. Although a DSnB catheter equipped with a check valve prevented backflow in the *in vitro* study, no difference in new bacterial growth of residual urine after OCD for 10 h was observed between DSnB catheters equipped with or without check valves *in vivo*. Moreover, residual urine volume tended to be greater for DSnB catheters with check valves than for those without check valves.

The efficacies of NBE (2, 3), COCD (4) and OCD (5) in addition to CIC during daytime have been reported. These approaches prevent vesicoureteral reflux and dilation of the urinary tract, and preserve renal function by avoiding overdistention of the bladder and maintaining low intravesical pressure during nighttime. Although NBE (2, 3), COCD (4) and OCD (5) have been used mainly for school-aged children, the importance of earlier intervention in patients with poor bladder function has been recognized (2-5). Intervention is needed for infants with spina bifida (5), but reusable indwelling balloon catheters for use in infants and younger children are unavailable in Japan.

We have previously performed continuous urine drainage from the bladder using a custom-made reusable 8-Fr temporary indwelling balloon catheter in a 5-year-old boy

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with spina bifida as a variation of NBE (2, 3) or COCD (4), because of frequent upper urinary tract infections (uUTIs) despite optimal CIC. However, use of the indwelling balloon catheter was discontinued for the following reasons: 1) the custom-made nature of the catheter made this method expensive; 2) the catheter carried a risk of uUTIs because of repeated long-term use; 3) inflating and fixing the balloon of the indwelling catheter was complicated for the patient's family; and 4) rolling over and body movements during nighttime sleep risked urethral injury and entanglement of the indwelling catheter and urinary collecting bag.

We therefore adopted safer and simpler OCD using a DSnB catheter fitted with a tapered adapter for infants and young children who roll over and move frequently during sleep. In OCD, the distal end of the straight catheter outside the body is simply fixed with tape and opens into a diaper, minimizing the risk of urethral injury. A similar method has been reported with an indwelling balloon catheter without an inflating balloon, fixed to the body surface with elastic tape to reduce urethral injury and contact with foreign substances in NBE (3). Additional advantages of a DSnB catheter were the low cost and cleanliness of using disposable daily-use catheters, and the tapered adapter of the DSnB catheter was effective in preventing straying into the bladder. In COCD (4), other advantages include: 1) uninterrupted sleep when the bladder drains continuously at night, offering a significant improvement in quality of life; 2) improved quality of life for both parents in not having to wake during the night for CIC; 3) resolution of the problem of urine leakage and bed soiling; and 4) facilitation of the morning routine by not needing to catheterize on rising and before leaving for school.

Although DSnB catheters could maintain low intravesical pressure regardless of the presence or absence of a check valve, absence of check valves readily resulted in

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backflow via the DSnB catheter when negative pressure similar to physiological changes in intraabdominal pressure was applied *in vitro*. We therefore conducted the *in vivo* study to evaluate the utility of a check valve for DSnB catheters. However, no significant difference in new bacterial growth in urine was seen between using DSnB catheters equipped with and without check valves. This result suggests that the risk of retrograde infection via the outside of DSnB catheters, but not the inside, could not be ruled out, supporting the findings of indwelling catheter-associated urinary tract infection (CAUTI) as widely recognized in practice (6, 7). CAUTI is mostly caused by retrograde infection via the inside and outside of an indwelling catheter (8), such as in cases where bacteria that have formed colonies invade the bladder by traveling along the outer surface of the indwelling catheter, and sterilization procedures at catheter insertion are inadequate. The risk of CAUTI increases with the duration of the indwelling catheter in the bladder, and is considered to increase by 5% each day (9). Removing unnecessary indwelling catheters as early as possible is thus recommended, and short-term catheterization for 10-12 h (overnight) such as with NBE (2, 3), COCD (4) and OCD (5) might reduce the risk of uUTIs (3). In addition, ensuring continuous flow of urine was considered important for preventing uUTIs (6), and increased residual urine volume has been linked to a higher risk of uUTIs (10). DSnB catheters without check valves tended to have lower residual urine volume after 10-h OCD *in vivo* and may thus be better suited to practical use. In addition, recent advances in diapers using highly absorbent materials might help the method with the distal end of the DSnB catheter outside the body opening into diapers to prevent the backflow of contaminated urine (11).

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Some limitations in the present study must be taken into consideration. Use of non-physiological excised swine bladder *in vitro* and use of healthy rabbits showing normal micturition *in vivo* might not adequately represent neurogenic bladder due to spina bifida in human infants. However, both *in vitro* and *in vivo* experiments showed that DSnB catheters without check valves drained urine from the bladder well, which could indicate maintenance of low intravesical pressure and deflation of the bladder without much residual urine in clinical use. In addition, the present study did not examine the effects of repeated catheterizations as seen with daily clinical use, which might still increase the risk of uUTIs. However, because we adopted a disposable catheter rather than a reusable indwelling catheter, repeated catheterization might not markedly increase the risk of uUTIs.

Conclusions

A simple open drainage system using disposable no-balloon indwelling catheters opening into diapers maintained low intravesical pressure and reduced residual urine volume. Installing check valves in DSnB catheters did not decrease new bacterial growth, but did tend to increase residual urine volume. In clinical use, DSnB catheters without check valves appear appropriate for continuous drainage of urine from the bladder.

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Conflicts of interest: The authors declare no conflict of interest.

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Ethical Approval: These experiments were approved by the animal experimental ethics committee at Iwate Medical University (No 26-033).

Author contributions:

H.F., K.I., K.O., and S.C. designed this experimental studies ; H.F., K.I., S.T., S.N., M.S. and A.T. performed experiments; H.F., K.I., and A.T. collected and analyzed data; H.F., and K.I. wrote the manuscript; K.O. and S.C. gave technical support and conceptual advice. All authors read and approved the final manuscript.

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Figure legends

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b: Each rabbit is fitted with a dedicated vest to prevent the diaper from falling off.

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