The Safety and Efficacy of the Indwelling Valve Catheters in the Long-term Catheterised Patients: A Systematic Comparative Study

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Key Words

Valve catheter • Non-valve catheter • Safety • Efficacy

Abstract

Introduction: There is paucity of data regarding the safety and efficacy of the valve catheters (VC). We aimed to prospectively evaluate our experience in regards to the safety and efficacy of the VC and compared it to patients with non-valve catheters (NVC). **Methods:** Total 76 male patients were included in both the VC and NVC groups. The type of catheters was standardized by using Bard® manufacturer, United Kingdom. Patients were evaluated 4–6 weeks following catheterization by filling out a non-validated quality of life (QoL) questionnaire at their scheduled clinic visit. **Results:** Mean age was 75 years (range 62–85 years) and 77 years (range 66–88 years) in the VC and NVC groups respectively. There were comparable results of the VC and NVC groups. However, observed benefits were found in regards to the ease (4/5-point scale: 64% in VC and 53% in NVC), comfort of usage (4/5-point scale: 59% in VC and 54% in NVC), patient's confidence (very confident: 95% in VC and 82% in NVC) ($p > 0.05$). Three bladder spasms were recorded in the VC group, compared to 2 in the NVC group. In contrast, only 1 urinary tract infection observed in the VC group, compare to 2 in the NVC group ($p > 0.05$). **Conclusions:** This study demonstrates that VC is a viable and patient friendly alternative. This may be partly explained by the functional mechanism of the VC mimicking the urinary bladder sphincters. Future research should aim to further improve its mechanical functionality.

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Introduction

Bladder drainage via indwelling catheters is usually indicated in patients with short-term bladder outlet obstruction such as benign prostatic hyperplasia (BPH). However, failing the utilization of intermittent self-catheterization, a long-term form of bladder drainage is often directed to elderly patients with neurogenic bladders [1, 2]. Neurogenic bladder can result from a wide range of causes such as inflammatory, ischemic and traumatic i.e. transverse myelitis, cerebro-vascular accidents and spinal injuries [1, 2]. Continuous bladder drainage via an indwelling catheter attached into a leg bag i.e. non-valve catheters (NVC) remains an effective method of emptying the bladder for many patients. More recently, there has been increasing evidence in the published literature and clinical practice to support using an alternative method of bladder drainage such as valve catheters (VC). A VC is a small drainage tap that fits into the end of the indwelling catheter. Hence, urine is stored in the bladder rather than in a bag attached to the leg which maintains bladder muscle tone and pressure and allowing cycling of the bladder by releasing the valve on regular intervals [1–3].

The introduction of VC has given catheterized patients choice and widened the range of therapeutic interventions that are available, particularly, reduced urinary tract infection (UTI), maintenance of bladder tone, function and capacity as well as patient's preference [4–6]. Previous studies have described the 'flushing effect' which may reduce infection when the bladder is emptied periodi-

Fig. 1. Schematic drawing of the valve catheter (Flip-Flo®, Bard Ltd, UK) demonstrating the mechanical valve attachment with the indwelling urinary catheter (urinary bag not attached).

Table 1. Patients' demographics and details in the VC and NVC groups

	VC	NVC
Patients, n	38 (100%)	38 (100%)
Mean age (range), years	75 (62–85)	77 (65–88)
Sex	Male (100%)	Male (100%)
Catheter manufacturer	Bard, UK	Bard, UK
Follow-up period, weeks	4–6	4–6

cally. Where infection exists, catheter blockage is probable therefore the same 'flushing effect' may, in theory, reduce blockages [4–6]. Regarding comfort, numerous studies agree that the VC is superior to the NVC. Notably, NVC has the potential to create heat rash although some bags have a fabric backing or sleeve to prevent this effect to some limited extent. Furthermore, vast majority of the VC including Flip-Flo® (Bard, United Kingdom), have the potential to form a link system, allowing the patient to easily attach urinary collecting bag to drain urine out [4–6].

We sought to prospectively evaluate the safety and efficacy of the VC in elderly men with long-term catheters and compare it prospectively to patients with NVC.

Patients and Methods

Over a year period, a total of 76 male patients were included in both the VC and NVC groups (38 male patients in each group).

All patients required acceptable dominant hand function to manage their respective urinary catheters. The hand functions were clinically assessed by the table top test in each patient. The type of VC and NVC was standardized by using Bard® manufacturer, United Kingdom (UK) (fig. 1). No patients in both groups developed UTIs in the year period preceded the utilization of the urinary catheters. Patients were evaluated 4 to 6 weeks following catheterization by filling out a non-validated quality of life (QoL) questionnaire given by urology specialist nurse at their scheduled clinic visit (appendix 1). The QoL questionnaire was designed to record VC and NVC performances by patients on their scheduled review dates. Patients' demographics and details are summarized in table 1.

QoL questionnaire consisted of the level of satisfaction, easy of use, hand function, valve open and closing function, comfort of use, inconspicuous, patient confidence using catheter valve at social places were all scored against 5-point scale of excellent, very good, good, fair and poor. The frequency and treatment of bladder spasm and/or by-passing/blockages of the catheters were also assessed. The frequency of changing the catheters in both groups was also observed as well as the utilization of nocturnal urinary drainage bags. When clinically indicated, urinalysis and/or urine cultures were also performed by the urology nurse. The presence of UTIs from a catheter specimen of urine and subsequent antimicrobial treatment were also recorded. Comparative analysis between the 2 groups was performed using Fisher's exact. P value < 0.05 considered to be statistically significant. All data were collected and stored electronically. Comparative results are summarized in table 2.

Results

Mean age of the VC group was 75 years (range 62–85 years), whereas mean age of the NVC group was 77 years (range 66–88 years). The majority of patient's level of satisfaction was recorded as 4/5-point scale in 53% of the VC group and 51% of the NVC group ($p > 0.05$). Higher number of patients found the usage of the VC easier (4/5-point scale), compared to the usage of NVC (64 and 53% respectively) ($p > 0.05$). Dominant hand function was observed as good function in all patients (3/5-point scale) and valve open and closing mechanism of the VC was also assessed and found to be very good (4/5-point scale) in 53% of patients. Comfort of usage was found to be very good (4/5-point scale) in 59% of VC group and 54% of NVC group ($p > 0.05$). Similarly, inconspicuous was also higher in the VC group (very good, 4/5-point scale) at 63%, compared to the NVC group (very good, 4/5-point scale) at 53% ($p > 0.05$). Ninety-five percent of patients were very confident of utilizing the VC, compared to 82% in the NVC group ($p > 0.05$).

Bladder spasms was recorded in 3 patients (8%), ranged between 2 and 6 spasms per day in the VC group, compared to 2 patients (5%), ranged between 1 and 4 spasms

Table 1. Comparative results of the VC and NVC groups

	VC	NVC	p
Level of satisfaction	38 (100%)	38 (100%)	> 0.05
Excellent	4 (11%)	4 (11%)	
Very good	20 (53%)	19 (51%)	
Good	10 (25%)	10 (25%)	
Fair	4 (11%)	5 (13%)	
Poor	0 (0%)	0 (0%)	
Ease of usage	38 (100%)	38 (100%)	> 0.05
Excellent	4 (11%)	2 (5%)	
Very good	24 (64%)	20 (53%)	
Good	10 (25%)	10 (25%)	
Fair	0 (0%)	6 (17%)	
Poor	0 (0%)	0 (0%)	
Dominant hand function	38 (100%)	38 (100%)	> 0.05
Excellent	0 (0%)	0 (0%)	
Very good	0 (0%)	0 (0%)	
Good	38 (100%)	38 (100%)	
Fair	0 (0%)	0 (0%)	
Poor	0 (0%)	0 (0%)	
Valve open and closing	38 (100%)	NA	NA
Excellent	4 (11%)		
Very good	20 (53%)		
Good	10 (25%)		
Fair	4 (11%)		
Poor	0 (0%)		
Comfort of usage	38 (100%)	38 (100%)	> 0.05
Excellent	4 (11%)	0 (0%)	
Very good	22 (59%)	20 (54%)	
Good	10 (25%)	10 (25%)	
Fair	2 (5%)	8 (21%)	
Poor	0 (0%)	0 (0%)	
Inconspicuous	38 (100%)	38 (100%)	> 0.05
Excellent	3 (8%)	0 (0%)	
Very good	23 (61%)	20 (53%)	
Good	11 (29%)	10 (25%)	
Fair	1 (2%)	4 (11%)	
Poor	0 (0%)	4 (11%)	
Patient's confidence	38 (100%)	38 (100%)	> 0.05
Very	36 (95%)	31 (82%)	
Less	2 (5%)	6 (16%)	
None	0 (0%)	1 (2%)	
Bladder spasms			> 0.05
No. patients developed spasms	3 (8%)	2 (5%)	
No. spasms (range)/24hrs	2–6	1–4	
Anti-cholinergic treatment alone	2	1	
Anti-spasmodic treatment alone	1	1	
Combined treatment	0	0	
Catheter blockages	0 (0%)	0 (0%)	> 0.05
ED attendance	1 (2%)	2 (5%)	> 0.05
Catheter change			> 0.05
Frequency	6–8 weeks	6–8 weeks	
General practitioner	7 (18%)	10 (25%)	
Emergency department	1 (2%)	2 (5%)	
Public nurse	30 (80%)	26 (70%)	
Nocturnal urinary bag	36 (95%)	38 (100%)	> 0.05
Urinary tract infections			> 0.05
Frequency	1 (2%)	2 (5%)	
Bacterial growth/type	0 (0%)	1 (2%)/ <i>E. coli</i>	
Anti-microbial treatment/type	0 (0%)	1 (2%)/ciprofloxacin and gentamicin	

NA = Not available.

per day in the NVC group. Three patients required treatment for bladder spasms in the VC group, compared to 2 patients in the NVC group. Anti-cholinergic medications was prescribed in 2 patients in the VC group, whereas, only 1 patient was on anti-cholinergic in the NVC group. Anti-spasmodic was prescribed in 1 patient only in each group. No patient required combined therapy. Time of catheter change was usually after 6–8 weeks and commonly preformed by the public nurse (80% in the VC group and 70% in the NVC group) ($p > 0.05$).

Ninety-five percent of patients utilized nocturnal urinary bag to manage their VC, hence avoiding the trip to bathroom during the nighttime. One patient developed UTI with no identified bacterial growth in the urine in the VC group, compared to 2 patients in the NVC group ($p > 0.05$). Among the 2 patients developed UTIs in the NVC group, 1 patient had *E. coli* UTI requiring anti-microbial medications of ciprofloxacin and gentamicin.

Discussion

Although, there is a paucity of research-based literature on VC, an increasing body of evidence suggests that many patients would prefer a VC over a NVC, in particular to level of satisfaction and comfort [6–13]. Adding to this, numerous comparative studies have aimed to compare the use of VC to NVC and conclusions have been drawn that the VC was extremely acceptable to the catheterized patients with no significant difference in the prevalence of catheter-related complications, particularly the development of UTIs. It is also believed that the ‘flushing effect’ of VC may reduce the development of UTIs when the bladder is emptied periodically and frequently. Wilson et al. [12] compared different types of catheters and found less prevalence of cross-infection among VC groups.

German et al. [9] conducted a randomized, crossover trial of VC versus NVC on 16 male patients over 3-week period. They found that the VC was more comfortable than the NVC during walking and enabled more natural voiding mechanism. However, in the VC group, there was more nocturnal frequency and episodes of urge incontinence observed. Additionally, they concluded that the ideal management would be a VC during the day and a nocturnal urinary bag for drainage. It was also reported that the NVC had the potential to create heat rash on the thigh or upper leg area.

Fader et al. [3] have shown that the CV can be both utilized urethrally or suprapubically. The VC can also al-

low men to use a urinal standing up to empty their bladders [9]. In a study by Bard manufacturer, patients who regularly utilized the VC achieved better voiding restoration following their prostate surgery i.e. transurethral resection of prostate [1]. On removal of the VC, the restoration of normal or near normal voiding functions can be partly explained by the maintenance of the bladder tone generated by the VC mechanism [11, 13].

Generally, the use of catheters may cause trauma to the bladder as well as urethra. Roe et al. [8] described erosions of the bladder mucosa caused by catheter’s irritation and actual sores can develop in the bladder, caused by the friction of a catheter. The VC may reduce this risk by periodically lifting the bladder wall away from the catheter and allowing the bladder to refill. Additionally, bladder neck traction may also be minimized by the VC [2].

Previous reported studies have shown that bladder shrinkage can manifest after a period of 6 months or over if on continuous urinary drainage ensured by NVC [4]. In patients utilizing VC, bladder function, capacity and tone can be maintained [1]. However, the long-term usage of the VC can eventually lead to development of bladder spasms (detrusor instability), by-passing of catheter and catheter blockages [8, 9]. It is also worth mentioning that VC should be avoided in patients with known vesico-ureteric reflux and chronic renal impairment [3, 6].

In the present study, there have been comparable results of the VC and NVC groups (table 2). However, potential benefits were observed in regards to the ease, comfort of usage, patient’s confidence in the VC group compared to the NVC group. Although, more bladder spasms occurred in the VC group, all patients responded very well to the medical treatment. In contrast, there were more UTIs developed in the NVC, in comparison to the VC group.

The observed benefits of the clinical utilization of the VC can be partly due to their functional mechanism which mimics the normal physiological control of the urinary bladder sphincters. Moreover, the dexterity functions of the patients using VC need to be assessed in order to achieve satisfactory results.

Conclusion

The VC is a viable and patient-friendly alternative to the NVC in patients with long-term catheters. Future research studies should be directed to further improve the function of VC, perhaps with utilization of electrical sen-

ing trail without VC and/or surgery should also be considered as end-points in the future studies.

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