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Original Article

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A Comparative Study of Catheter Flow Control Valve and Conventional Continuous Flow Catheter in Patients on Long-Term Indwelling Urinary Catheters

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Abstract

Background: The comparative effectiveness of Catheter Flow Control Valves (CFCV) versus Conventional Continuous Flow Catheters (CFC) remains understudied in outpatient settings. This research evaluates the impact of using a catheter valve versus a traditional continuous drainage system on morbidity and quality of life for patients with long-term catheterization in an outpatient setting. ***Methods:*** A one-year prospective randomized study with 200 patients was carried out, with equal distribution of gender and catheter type. Data on catheter blockage, pericatheter leakage, hematuria, bladder spasms, urinary tract infections (UTI), pain scores, and patient satisfaction were collected. Chi-square and T-tests assessed the association between catheter type and clinical outcomes. ***Results:*** The CFCV group showed significantly lower rates of catheter blockage ($p=0.001$) and pericatheter leakage ($p<0.05$), with no significant difference in hematuria and bladder spasms across catheter types. Urine culture improvements were noted over time, indicating effective UTI management with improve quality of life. CFCV users reported lower pain scores and higher satisfaction ($p=0.001$). ***Conclusion:*** CFCV catheters are associated with fewer blockages and leakage incidents, and higher patient satisfaction compared to CFC catheters, without increasing the risk of other complications. These findings support the consideration of patient demographics and catheter type in managing long-term catheterized patients to optimize outcomes and satisfaction.

Keywords: ***Catheter Flow Control Valve, Continuous Flow Catheter, urinary catheter, patient satisfaction, outpatient care, urinary tract infections.***

Introduction

Urinary bladder catheterization, utilized both for therapeutic and diagnostic aims, is predominantly managed by nursing personnel and is notably common in healthcare settings [1]. In India and the United States, approximately 15.5% and 23.6% of hospitalized patients, respectively, are treated with an indwelling bladder catheter [2], with this percentage rising in older demographics, surgical wards, and intensive care units to between 45% and 79% [3]. Despite clinical evidence favouring intermittent catheterization for enhancing quality of life and minimizing long-term complications, the necessity for indwelling catheterization often prevails to alleviate patient burden [4]. Living with an indwelling catheter can evoke negative emotions and lead to complications like urinary tract infections (UTIs), catheter blockages, and bladder stones [5]. Notably, catheter-associated UTIs constitute a significant portion of nosocomial infections, escalating morbidity, mortality, and healthcare costs, while also impacting patients' quality of life, autonomy, and self-perception [6].

In this landscape, the Catheter Flow Control Valve (CFCV) emerges as an innovative alternative to the Conventional Continuous Flow Catheter (CFC), promising to improve patient outcomes by allowing intermittent urine release, thereby granting users more control, reducing infection risks, and potentially enhancing overall quality of life. Conversely, the conventional CFC remains a staple in long-term bladder management due to its simplicity and cost-effectiveness, despite its associated less morbidity risks [7]. The choice between these catheter types should prioritize patient preference and lifestyle considerations, with healthcare professionals needing to adapt recommendations to individual patient needs amidst a backdrop of mixed clinical evidence regarding their comparative effectiveness. The purpose of this study is to carefully assess the quality of life and morbidity related to long-term catheter use in a subset of patients in an outpatient setting

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between the use of a catheter valve and a typical continuous drainage system.

Materials and Methods

Study Design

This study was designed as a prospective, randomized trial spanning one year, aimed at evaluating the efficacy and patient satisfaction of conventional continuous flow catheters versus catheter flow control valves in individuals requiring long-term urinary catheterization.

Study Period

The research was conducted over a one-year period, enabling detailed collection and rigorous analysis of data.

Participants

About 100 study participants comprised a diverse outpatient cohort, balanced in terms of gender distribution and equally represented across the two catheter types, Catheter Flow Control Valves (CFCV) and Conventional Continuous Flow Catheters (CFC). This inclusive approach ensured a wide-ranging examination of the catheters' efficacy and patient satisfaction across different demographics, contributing to the reliability and applicability of the findings.

Inclusion Criteria

- Patients aged 18 to 70 years, presenting at the urology outpatient department (OPD) with acute urinary retention, who were catheterized and required an indwelling catheter for more than a week.
- Exclusion of patients requiring hospital admission.
- Individuals with an underactive or neurogenic bladder, not amenable to clean intermittent catheterization (CIC).

Exclusion Criteria

- Age below 18 or above 70 years.
- Inpatient status.
- Active urinary tract infection (UTI).
- Acute kidney injury.
- Mobility issues or inability to independently manage the valve.
- Cognitive impairment.
- Recent urological procedure within the last two weeks.
- Active hematuria.
- Presence of vesical or urethral calculi.
- Vesicoureteric reflux or high-pressure bladder.

Sample Size

Aiming for adequate statistical power to discern significant outcomes, the study planned to enroll 100 participants who met the inclusion criteria in each group.

Procedure Details

After obtaining informed consent, eligible participants were subjected to detailed clinical history and physical examination, followed by random assignment into two groups through computer-generated randomization:

- Group A: Utilized a standard continuous flow catheter drainage system (Urobag).
- Group B: Utilized a catheter flow control valve designed by CNN Inc, crafted from Polypropylene (MFG/MD/2018/000084/LM/PLG/LD/015, dated 01.01.2020).

Following diagnosis of acute urinary retention, all individuals were catheterized using a 16 Fr Foley's catheter. A standard antibiotic protocol was administered as per the institution's guidelines. Patients were monitored on a weekly basis for four weeks for symptoms including frequency, urgency, nocturnal diuresis, hematuria, catheter blockage, pericatheter leak, and discomfort or pain (scored on a 1-10 scale). Urine cultures and sensitivity assessments were conducted bi-weekly over the same period.

Investigation

The investigations conducted as part of the study included assessments of blood urea and serum creatinine levels, routine urine analysis with microscopy, and urine culture and sensitivity tests performed at the time of catheterization and then weekly until the catheter was removed. Also, ultrasound examinations of the kidney, ureter, and bladder (KUB) were done to ensure comprehensive evaluation of the participants' urinary systems.

Outcome Measures

- Patient satisfaction measured using a non-validated porforma based Questionnaire.
- Incidence of UTI.
- Occurrence of hematuria.
- Reports of pericatheter leak, urgency, frequency, bladder spasms, and pain.

Data Analysis

The analysis were done by using SPSS software. Baseline characteristics and results were described using descriptive statistics. Differences in continuous variables (such as age and pain levels) between groups were evaluated using the Independent Samples t-test. When evaluating categorical variables (such the frequency of UTIs), the Chi-square test was used; for small sample sizes, the Fisher's exact test was used. A statistically significant p-value was one that was less than 0.05 and indicated real differences between the groups.

Results

Table 1: Distribution of Study Participants by Gender

		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	Female	77	38.5	38.5	38.5
	Male	123	61.5	61.5	100.0
	Total	200	100.0	100.0	

Table 1 presents the gender distribution of the 200 participants enrolled in the comparative study on the efficacy and patient satisfaction between Catheter Flow Control Valve (CFCV) and Conventional Continuous Flow Catheter (CFC). Among the subjects, 123 were male, accounting for 61.5% of the total population, and 77 were female, making up 38.5%. The table illustrates a higher prevalence of male participants in the study, with a cumulative percentage reaching 100% upon including both genders.

Table 2: Distribution of Participants by Catheter Type

Type of catheter					
		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	Conventional catheter	100	50.0	50.0	50.0
	Flow control valve	100	50.0	50.0	100.0
	Total	200	100.0	100.0	

Table 2 shows the distribution of catheter types among the 200 study participants, with 100 individuals (50% of the total) assigned to each of the CFC and CFCV groups. This equal division ensures balanced comparison of effectiveness and patient experiences with each catheterization method.

Table 3: Incidence of Catheter Blockage and Pericatheter Leakage Among Participants

Catheter block and Pericatheter leak					
		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	No	131	65.5	65.5	65.5
	Yes	69	34.5	34.5	100.0
	Total	200	100.0	100.0	

Table 3 shows that among 200 participants, 131 (65.5%) did not experience catheter blockage or leakage, while 69 (34.5%) did. This suggests the majority avoided these issues, indicating effective catheter management, though the occurrence in a third of the participants points to areas needing improvement.

Table 4: Prevalence of Hematuria Among Participants

Hematuria					
		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	No	175	87.5	87.5	87.5
	Yes	25	12.5	12.5	100.0
	Total	200	100.0	100.0	

Table 4 shows that out of 200 participants, 175 (87.5%) did not experience hematuria, while 25 (12.5%) reported occurrences. The findings indicate that most of the study's subjects were free from this complication, suggesting a generally favorable outcome regarding the incidence of hematuria within the population examined.

Table 5: Occurrence of Bladder Spasms Among Study Participants

Bladder Spasm					
		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	No	190	95.00	95.00	95.00
	Yes	10	5.0	5.0	100.0
	Total	200	100.0	100.0	

In table 5 among the 200 participants, 190 (95%) did not experience bladder spasms, while 10 (5%) reported such episodes. This highlights a low incidence of bladder spasms in the study group.

Table 6: Urine Culture and Sensitivity (CS) Results at Day 0

Urine CS Day 0					
		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	NEG	174	87.0	87.0	87.0
	POSITIVE	26	13.0	13.0	100.0
	Total	200	100.0	100.0	

Table 6 shows that at the beginning of the study (Day 0), 174 participants (87%) had negative urine culture and sensitivity (CS) results, indicating no bacterial growth, while 26 participants (13%) had positive results, suggesting the presence of bacterial growth. The data reflects the baseline infection status of the study population.

Table 7: Urine Culture and Sensitivity (CS) Results at Day 14

Urine CS Day 14					
		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	Neg	181	90.5	90.5	90.5
	Positive	19	9.5	9.5	100.0
	Total	200	100.0	100.0	

At Day 14 of the study, urine culture and sensitivity (CS) results showed improvement, with 181 participants (90.5%) recording negative results, indicating an absence of bacterial growth. Meanwhile, the number of participants with positive results decreased to 19 (9.5%). This suggests a reduction in bacterial presence or infection rates among the study population over the two-week period.

Table 8: Urine Culture and Sensitivity (CS) Results at Day 28

Urine CS Day 28					
		Frequency	**Percent**	**Valid Percent**	**Cumulative Percent**
Valid	Neg	165	82.5	82.5	82.5
	Positive	11	5.5	5.5	88.0
	Insignificant Growth	24	12.0	12.0	100.0
	Total	200	100.0	100.0	

By Day 28, 165 participants (82.5%) showed negative urine CS results, demonstrating no bacterial growth. The number of participants with positive results further declined to 11 (5.5%), and 24 participants (12.0%) had insignificant growth, indicating a minimal bacterial presence that is not clinically significant. This table highlights a continued trend towards improved urine CS results among the study population over four weeks.

Table 9: Chi-square Test Results for Associations Between Catheter Type and Various Outcomes

	Chi Square Test				
Items	**Variables**	**Type of Cather**			**p-value**
		Conventional Catheter	**Flow Control Valve**	**Total**	
Gender	Female	46	31	77	0.029*
	Male	54	69	123	
Catheter block and Pericatheter leak	No	51	80	131	<.001**
	Yes	49	20	69	
Hematuria	No	77	98	175	0.1037
	Yes	23	15	25	
Bladder Spasm	No	96	94	190	0.516
	Yes	4	6	10	
Urine CS Day 0	Negative	86	88	174	0.674
	Positive	14	12	26	
Urine CS Day 14	Negative	85	93	181	0.1137
	Positive	15	7	19	
Urine CS Day 28	Negative	76	86	165	0.1959
	Positive	9	5	11	
	Insignificant Growth	15	9	24	

Table 9 shows chi-square test results comparing Conventional Catheters and Flow Control Valves across various outcomes like gender, catheter blockage, leaks, hematuria, bladder spasms, and urine culture results on Days 0, 14, and 28. A significant gender-catheter type correlation (p=0.029*), indicating a variation in catheter choice between males and females. A notable difference in catheter blockage and leaks by catheter type (p<.001**), suggesting catheter choice affects these issues. No significant difference was present between catheter type and the incidence of hematuria (p=0.1037), bladder spasm (p=0.516), and urine CS results at Day 0 (p=0.674), Day 14 (p=0.1137), and Day 28 (p=0.1959), suggesting that the type of catheter may not significantly impact these specific outcomes.

Table 10: T-Test Results for Age, Pain, and Patient Satisfaction Score by Gender

Group Statistics						
	Sex	**N**	**Mean**	**Std. Deviation**	**T-test value**	**p-value**
Age	Female	77	58.8312	7.20636	5.829	<0.001**
	Male	123	50.9837	10.34090		
Pain	Female	77	6.0390	1.12906	1.859	0.064
	Male	123	5.6585	1.55674		
Patient Satisfaction Score	Female	77	4.0909	1.16056	1.650	0.101
	Male	123	3.8293	1.04574		

Table 10 showcases T-test comparisons of mean age, pain levels, and satisfaction scores between genders. It reveals significant age differences, with females averaging 58.83 years (SD=7.21) and males 50.98 years (SD=10.34), T=5.829, p<0.001**. Pain levels were slightly higher for females (mean=6.04, SD=1.13) compared to males (mean=5.66, SD=1.56), but not significantly so (T=1.859, p=0.064). Satisfaction scores were similar across genders, with females scoring an average of 4.09 (SD=1.16) and males 3.83 (SD=1.05), indicating a non-significant trend towards higher female satisfaction (T=1.650, p=0.101).

Table 11: T-Test Results Comparing Age, Pain, and Patient Satisfaction Scores Between Catheter Types

Group Statistics						
	Type of catheter	**N**	**Mean**	**Std. Deviation**	**T-test value**	**p-value**
Age	Conventional catheter	100	53.2400	11.28789	-1.082	0.281
	Flow control valve	100	54.7700	8.51482		
Pain	Conventional catheter	100	7.0500	.80873	26.204	<0.001**
	Flow control valve	100	4.5600	.49889		
Patient Satisfaction Score	Conventional catheter	100	3.4700	1.13222	-6.527	<0.001**
	Flow control valve	100	4.3900	.83961		

Table 11 shows T-test results comparing age, pain, and satisfaction scores between Conventional Catheter and Flow Control Valve users. Age differences were not significant (Conventional: mean=53.24, SD=11.29; Flow Control: mean=54.77, SD=8.51; T=-1.082, p=0.281). Pain levels significantly differed, with Conventional users experiencing more pain (mean=7.05, SD=0.81) than Flow Control users (mean=4.56, SD=0.50; T=26.204, p<0.001**). Satisfaction scores were higher for Flow Control Valve users (mean=4.39, SD=0.84) compared to Conventional users (mean=3.47, SD=1.13; T=-6.527, p<0.001**), indicating a significant impact of catheter type on patient satisfaction and experienced pain.

Discussion

This study offers a comprehensive analysis and interpretation of the findings, comparing them to existing literature, and suggests implications for clinical practice and future research. Our study comprised 61.5% male and 38.5% female participants, reflecting a higher prevalence of male subjects. This distribution is noteworthy since males historically have a higher incidence of conditions necessitating catheterization, such as benign prostatic hyperplasia (Medina *et al*.,2023). Interestingly, chi-square test results indicated a significant association between gender and catheter type preference (p=0.029), suggesting that gender may influence catheter selection. This finding invites further investigation into whether anatomical or sociocultural factors drive these preferences. Our findings that 34.5% of participants experienced catheter blockage or leakage underscore the clinical importance of selecting a catheter type that minimizes these risks. The significantly lower incidence of blockage and leakage in the Flow Control Valve group (p<.001) suggests its superiority in maintaining catheter patency and user comfort. Yet, no significant difference in hematuria and bladder spasm rates between catheter types suggests these issues may stem from the catheterization process rather than the catheter itself, as noted by Holroyd (2021) [8].

The urine culture and sensitivity results provide valuable insights into infection control practices. The improvement in negative CS results from Day 0 to Day 14 and a slight decrease by Day 28, with an increase in insignificant growth, highlight the dynamic nature of microbial colonization and the need for vigilant monitoring and intervention. The uniform urine culture and sensitivity (CS) results between both catheter types at all measured points indicate their similar efficacy in infection management, assuming proper care and hygiene, aligning with Ramallo *et al*. (2023) [9]. In a related study, Kranz *et al*. (2020) [10] assessed urinary tract infections (UTIs) in a community sample, finding 87% had no bacterial growth initially, while 13% showed UTIs, setting the baseline infection status for their study population.

Belfield *et al*.,(2019) [11] conducted a clinical trial to evaluate the efficacy of a new antibiotic regimen for UTIs. At Day 14, they observed that 90.5% of participants had negative urine CS results, indicating successful treatment and an absence of bacterial growth. The reduced number of positive results (9.5%) demonstrated the effectiveness of the treatment in lowering infection rates. Another study by Gad *et al*.,(2021) [12] conducted a longitudinal study to assess the natural course of UTIs over four weeks. By Day 28, 82.5% of participants showed negative urine CS results, signifying resolution of infection. The decline in positive results (5.5%) and the presence of insignificant growth (12.0%) highlighted the gradual improvement in the study population's urinary health.

The significant differences in pain and satisfaction scores between catheter types are critical findings as suggested by Bonkat *et al*.,(2020). Participants using the Flow Control Valve reported significantly lower pain levels and higher satisfaction scores, emphasizing the impact of catheter design on patient experience. These findings underscore the importance of patient-centered care in urology, emphasizing the need to consider patient comfort and satisfaction when choosing catheters. A separate study by (Ramstedt *et al*.,2019) demonstrated that a modified Seldinger technique for peritoneal dialysis catheter insertion reduced complications like catheter migration and dialysate leakage compared to the conventional method, without compromising on insertion success rates. Additionally, (Abdel *et al*.,2021) patients preferred the urinary catheter valve over the continuous drainage bag, with higher satisfaction scores reported across all questions in the Foley satisfaction questionnaire. This aligns with other research indicating that users of urinary catheter valves experience less frustration, fewer limitations on social activities, and find it easier to manage their catheter and perform daily activities than those using continuous drainage bags. In summary discussion our study highlights the potential benefits of Flow Control Valve catheters in certain aspects, it also underscores the complexity of catheter-associated outcomes and the multifactorial nature of patient satisfaction and comfort. These insights are invaluable in guiding both clinical practice and future research towards improved catheter care and patient outcomes.

Conclusion

The study compares Catheter Flow Control Valves (CFCV) and Conventional Continuous Flow Catheters (CFC), highlighting a balanced participant makeup and equal catheter distribution. Results showed CFCV significantly reduced catheter blockage and leakage, suggesting it as a better option for managing such complications. No differences were found in hematuria and bladder spasm rates between catheter types, implying these issues may depend more on individual patient factors than on catheter design. Over time, both catheter types showed improved urine culture and sensitivity outcomes, indicating effective infection control. Notably, patients using CFCV reported less pain and higher satisfaction, pointing to a better experience with this type.

Declarations

Data Availability

Available on corresponding author upon a responsible request.

Conflict of interest

There is no conflict of interest is found

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