Condom Catheters versus Indwelling Urethral Catheters in Men: A Prospective, Observational Study

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To assess complications of condom catheters compared with indwelling urethral catheters, we conducted a prospective cohort study in two Veterans Affairs hospitals. Male patients who used a condom catheter or indwelling urethral catheter during their hospital stay were followed for one month by interview and medical record review. Participants included 36 men who used condom catheters and 44 who used indwelling urethral catheters. At least one catheter-related complication was reported by 80.6% of condom catheter users and 88.6% of indwelling catheter users (P = .32), and noninfectious complications (eg, leaking urine, pain, or discomfort) were more common than infectious complications in both groups. Condom catheter patients were significantly less likely than indwelling catheter patients to report complications during catheter placement (13.9% vs 43.2%; P < .001). Patients reported approximately three times more noninfectious complications than the number recorded in the medical record. *Journal of Hospital Medicine*. Published online only April 20, 2020. © 2020 Society of Hospital Medicine

Millions of patients use urinary collection devices. For men, both indwelling and condom-style urinary catheters (known as "external catheters") are commonly used. National infection prevention guidelines recommend condom catheters as a preferred alternative to indwelling catheters for patients without urinary retention[1,2] to reduce the risk of catheter-associated urinary tract infection (UTI). Unfortunately, little outcome data comparing condom catheters with indwelling urethral catheters exists. We therefore assessed the incidence of infectious and noninfectious complications in condom catheter and indwelling urethral catheter users.

PATIENTS AND METHODS

Study Overview

As part of a larger prospective, observational study,[3] we compared complications in patients who received a condom catheter during hospitalization with those in patients who received an indwelling urethral catheter. Hospitalized patients with either a condom catheter or indwelling urethral catheter were identified at two Veterans Affairs (VA) medical centers and followed for 30 days after initial catheter placement. Patient-reported data were collected during in-person patient interviews at baseline (within three days of catheter placement), and by in-person or phone interviews at 14 days and 30 days postplacement (Supplementary Appendix A and B). Questions were primarily closed-ended, except for a final question inviting open comments. Information about the catheter and any reported complications was also collected from electronic medical record documentation for each patient. Institutional review board approval was received from both participating study sites.

Data Collection and Inclusion Criteria

Hospitalized patients who had a condom or indwelling urethral catheter placed were eligible to participate if they met the following criteria: (1) were hospitalized on an acute care unit; (2) had a new condom catheter or indwelling urethral catheter placed during this hospital stay that was not present on admission; (3) had a device in place for three days or less; (4) were at least 18 years old; and (5) were able to speak English. Patients were excluded if they: (1) did not have the capacity to give consent or participate in the interview/assessment process; (2) refused to provide written informed consent to participate; or (3) had previously participated in this project.

As the larger study was focused on indwelling urethral catheter users, participants with a condom catheter were recruited from only one facility, while those with an indwelling urethral catheter were recruited from both hospitals. Indwelling catheter patients that had a possible contraindication to condom catheter use (such as urinary retention or perioperative use for a surgical procedure) were excluded to make the groups comparable. Any indication for condom catheterization was permitted.

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TABLE 1. **Study Participant Demographics and Baseline Characteristics (N = 80)**

Characteristic	Condom Catheter, N (%)	Indwelling Urethral Catheter, N (%)	*P* Value
Age in years, mean (SD)	71.4 (11.8)	70.7 (11.8)	.80[a]
Sex			
Male	36 (100)	44 (100)	NA
Race	31 (86.1)	34 (77.3)	.84
White	2 (5.6)	6 (13.6)	.25
African American	1 (2.8)	1 (2.3)	
American Indian or Alaskan Native	2 (5.6)	3 (6.8)	
Other/Unknown	0 (0)	3 (6.8)	
Hispanic			
Reason for Urethral Catheter Placement			
Incontinence	10 (27.8)	16 (36.4)	<.001[b]
Perioperative use for surgical procedure[b]	11 (30.6)	0 (0)	
Required prolonged immobilization	5 (13.9)	11 (25.0)	
Accurate measurement of urine output	2 (5.6)	17 (38.6)	
Urinary retention or bladder obstruction[b]	1 (2.8)	0 (0)	
Other or unknown[b]	7 (19.4)	0 (0)	
Urinary Catheter Duration of 3 days or less	29 (80.6)	36 (81.8)	.89

[a]*P* value calculated with *t*-test

[b]Patients that self-reported having an indwelling urethral catheter placed for perioperative use for a surgical procedure, urinary retention or bladder obstruction, or other were intentionally excluded from this analysis since it could be inappropriate to use a condom catheter in some of those patients. We did not, however, exclude any patients from the condom catheter group based on their self-reported indication for placement.

Information about catheter-related complications was collected from two sources: directly from patients and through medical record review. Patients were interviewed at baseline and approximately 14 days and 30 days after catheter placement. The follow-up assessments asked patients about their symptoms and experience over the previous two weeks. We also conducted a medical record review covering the 30 days after initial catheter placement.

Study Measures

A patient was considered to have an infectious complication in the medical record review if a medical professional documented a UTI (for condom catheter patients) or catheter-associated UTI (for indwelling urethral catheter patients) in the medical record. Patients who either reported being told they had a UTI or reported they had fever, chills, burning with urination, urinary frequency, urinary urgency, or other symptoms suggestive of an infection that required the patient to see a doctor were considered to have a self-reported infectious complication. Noninfectious complications included symptoms such as pain or discomfort, trauma, a sense of urgency or bladder spasms, blood in their urine, leaking urine after catheter removal, and difficulty with starting or stopping a urine stream. Secondary outcomes focused on patient perspectives about their devices, including sexual function.

Data Analysis

The primary outcome was the percentage of patients who experienced a complication related to a urinary catheter during the 30 days after the catheter was initially placed. Comparisons by group—condom versus indwelling catheter—were conducted using chi-square tests (Fisher's exact test when necessary) for categorical variables and the Student's *t*-test for continuous variables. All analyses were performed using SAS (Cary, North Carolina). All statistical tests were two-sided with alpha set to .05.

RESULTS

Of the 76 patients invited to participate after having a condom catheter placed, 49 consented (64.5%). Of those, 36 had sufficient data for inclusion in this analysis. The comparison group consisted of 44 patients with an indwelling urethral catheter. There were no statistically significant differences between the two groups in terms of age, race, or ethnicity (Table 1). There were statistically significant differences in patient-reported reasons for catheter placement, but these were due to the exclusion criteria used for indwelling urethral catheter patients.

Both patient-reported and clinician-reported (ie, recorded in the patient's medical record) outcomes are described in Table 2. In total, 80.6% of condom catheter users reported experiencing at least one catheter-related complication during the month after initial catheter placement compared with 88.6% of indwelling catheter users ($P = .32$). A similar number of condom catheter patients and indwelling urethral catheter patients experienced an infectious complication according to both self-report data (8.3% condom, 6.8% indwelling; $P = .99$) and medical record review (11.1% condom, 6.8% indwelling; $P = .69$).

At least one noninfectious complication was identified in 77.8% of condom catheter patients (28 of 36) and 88.6% of indwelling urethral catheter patients (39 of 44) using combined self-report and medical record review data (P = .19); most of

TABLE 2. **Specific Complications Associated with Condom and Indwelling Urethral Catheter Use during the First Month after Catheter Placement**

	Patient-Reported Complications			Complications in Medical Record[a]		
Specific Complication	**Condom Catheter, N (%)**	**Indwelling Urethral Catheter, N (%)**	***P* Value**	**Condom Catheter, N (%)**	**Indwelling Urethral Catheter, N (%)**	***P* Value**
Infectious Complication	*3 (8.3)*	*3 (6.8)*	*.99*	*4 (11.1)*	*3 (6.8)*	*.69*
Fevers, chills, burning with urination, urinary frequency, urgency, or other symptoms suggestive of an infection that required you to see a doctor	2 (5.6)	3 (6.8)	.99			
Told they had a urinary tract infection	3 (8.3)	2 (4.6)	.65			
Documented urinary tract infection[b]				4 (11.1)	3 (6.8)	.69
Noninfectious Complication	*27 (75.0)*	*38 (86.4)*	*.20*	*9 (25.0)*	*12 (27.3)*	*.82*
Pain, discomfort, bleeding, or other trauma during urinary catheter insertion	5 (13.9)	19 (43.2)	<.001			
Pain or burning when you urinate[c]	4 (12.1)	10 (23.3)	.21	0 (0)	1 (2.3)	.99
Pain or swelling in scrotum[c]	1 (3.1)	11 (25.6)	.009			
Pain or discomfort (not otherwise specified)	2 (5.6)	3 (6.8)	.99	0 (0)	3 (6.8)	.25
Pain, discomfort, bleeding, or other trauma during urinary catheter removal[c]	9 (40.9)	8 (42.1)	.99			
Difficulty with starting or stopping your urine stream[c]	13 (40.6)	12 (27.9)	.25	1 (2.8)	2 (4.5)	.99
Urgency or bladder spasms	11 (30.6)	15 (34.1)	.74			
Leaking urine[c]	9 (27.3)	15 (34.9)	.48	5 (13.9)	3 (6.8)	.46
Split or spraying stream of urine[c]	8 (24.2)	14 (32.6)	.43			
Blood in urine	1 (2.8)	7 (15.9)	.07	1 (2.8)	6 (13.6)	.12
Sexual problems[c]	4 (12.5)	2 (4.7)	.39			
Urinary retention[c]				2 (5.6)	4 (9.1)	.69
Inadvertent removal	2 (5.6)	0 (0)	.20	2 (5.6)	0 (0)	.19
Other device related complication	8 (23.5)	9 (20.5)	.74	2 (5.6)	2 (4.5)	.99
Total Infectious and Noninfectious Complications[d]	**27 (75.0)**	**38 (86.4)**	**.20**	**12 (33.3)**	**14 (31.8)**	**.89**

[a] The patients identified as having a complication through patient report were often different from the patients identified through medical record review. For example, two patients with an indwelling urinary catheter were identified by both self-report and medical record review as having an infectious complication, however only one patient with a condom catheter was identified as having an infectious complication using both methods.

[b] The following definition was used for UTI documented in the medical record: "Any explicit statement of a diagnosis of UTI by a medical professional documented in the medical record as occurring after the use of a urinary catheter.

[c] These complications were assessed only for patients if they no longer had a catheter in place. All other complications were assessed in all patients, both with and without a current urinary catheter.

[d] For patient reported outcomes, all the patients that reported an infectious complication also reported a noninfectious complication. As a result, the total for both infectious and noninfectious complications is the same as for only noninfectious complications.

these were based on self-reported data. Significantly fewer condom catheter patients reported complications during placement (eg, pain, discomfort, bleeding, or other trauma) compared with those with indwelling catheters (13.9% vs 43.2%, $P < .001$). Pain, discomfort, bleeding, or other trauma during catheter removal were commonly reported by both condom catheter and indwelling urethral catheter patients (40.9% vs 42.1%, respectively; $P = .99$).

Patient-reported noninfectious complications were often not documented in the medical record: 75.0% of condom catheter patients and 86.4% of indwelling catheter patients reported complications, in comparison with the 25.0% of condom catheter patients and 27.3% of indwelling urethral catheter patients with noninfectious complications identified during medical record review.

DISCUSSION

Our study revealed three important findings. First, noninfectious complications greatly outnumbered infectious complications, regardless of the device type. Second, condom catheter users reported significantly less pain related to placement of their device compared with the indwelling urethral catheter

group. Finally, many patients reported complications that were not documented in the medical record.

The only randomized trial comparing these devices enrolled 75 men hospitalized at a single VA medical center and found that using a condom catheter rather than an indwelling catheter in patients without urinary retention lowered the composite endpoint of bacteriuria, symptomatic UTI, or death.[4] Additionally, patients in this trial reported that the condom catheter was significantly more comfortable (90% vs 58%; $P = .02$) and less painful (5% vs 36%; $P = .02$) than the indwelling catheter,[4] supporting a previous study in hospitalized male Veterans.[5]

Importantly, we included patient-reported complications that may be of concern to patients but inconsistently documented in the medical record. Pain associated with removal of both condom catheters and indwelling urethral catheters was reported in over 40% in both groups but was not documented in the medical record. One patient with a condom catheter described removal this way: "It got stuck on my hair, so was hard to get off…" Condom catheters also posed some issues with staying in place as has been previously described.[6] As one condom catheter user said: "When I was laying down it was okay, but every time I moved around…it would slide off."

Recent efforts to reduce catheter-associated UTI,[7-9] which have focused on reducing the use of indwelling urethral catheters,[10,11] have been relatively successful. Clinical policy makers should consider similar efforts to address the noninfectious harms of both catheter types. Such efforts could include further decreasing any type of catheter use along with improved training of those placing such devices.[12] Substantial improvement will require a systematic approach to surveilling noninfectious complications of both types of urinary catheters.

Our study has several limitations. First, we conducted the study at two VA hospitals; therefore, the results may not be generalizable to a non-VA population. Second, we only included 80 patients because we recruited a limited number of condom catheter users. Third, although we tried to compare two similar groups of patients, it is possible that indwelling catheter patients had greater morbidity, which necessitated the use of an indwelling catheter instead of a condom catheter. Finally, we found a large discrepancy between what our patients reported and the information gained from a review of their medical records. While complications reported by the patient may not constitute a medically defined complication, due to the well-known phenomenon of poor documentation of catheter complications in general,[13] we believe that what patients report is important for understanding the full scope of potential problems.

Limitations notwithstanding, we provide comparison data between condom and indwelling urethral catheters. Condom catheter users reported significantly less pain related to initial placement of their device compared with those using an indwelling urethral catheter. For both devices, patients experienced noninfectious complications much more commonly than infectious ones, underscoring the need to systematically address such complications, perhaps through a surveillance system that includes the patient's perspective. The patient's voice is important and necessary in view of the apparent underreporting of noninfectious harms in the medical record.

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