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Exploring Relationships of Catheter Associated Urinary Tract Infection and Blockage in People with Long-Term Indwelling Urinary Catheters

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Abstract

Aims—The aims were to describe and explore relationships among catheter problems in long-term indwelling urinary catheter users, including excess health care utilization for treating catheter problems.

Background—Long-term urinary catheter users experience repeated problems with catheter-related urinary tract infection (CAUTI) and blockage of the device, yet little has been reported of the patterns and relationships among relevant catheter variables.

Design—Secondary data analysis was conducted from a sample in a randomized clinical trial, using data from the entire sample of 202 persons over 12 months' participation.

Methods—Descriptive statistics were used to characterize the sample over time. Zero-inflated negative binomial models were employed for logistic regressions to evaluate predictor variables of the presence/absence and frequencies of CAUTI and blockage.

Results—CAUTI was marginally associated with catheter blockage. Problems reported at least once per person in the 12 months were: CAUTI 57%, blockage 34%, accidental dislodgment 28%, sediment 87%, leakage (bypassing) 67%, bladder spasms 59%, kinks/twists 42%, and catheter pain 49%. Regression analysis demonstrated that bladder spasms were significantly related to CAUTI and sediment amount, and catheter leakages were marginally significantly and positively related to CAUTI. Frequencies of higher levels of sediment and catheter leakage were significantly

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associated with higher levels of blockage, and being female was associated with fewer blockages. Persons who need help with eating (more disabled) were also more likely to have blockages.

Conclusions—CAUTI and blockage appear to be related and both are associated with additional health care expenditures. More research is needed to better understand how to prevent adverse catheter outcomes and patterns of problems in sub-groups.

Relevance to clinical practice—Nurses can develop care management strategies to identify catheter blockage prior to its occurrence by tracking the amount of sediment and frequency of leakage. Bladder spasms could be an early warning of CAUTI.

Keywords

urinary catheterization; blockage; nursing; catheter-associated urinary tract infection; complications

Catheter blockage and catheter-associated urinary tract infection (CAUTI) are the chief catheter related problems in long-term indwelling urinary catheter users, but little is known about how these problems are related. Each of these problems contributes to excess healthcare utilization (Wilde et al. 2013) and concern (Wilde 2003, Fowler et al. 2014). Other catheter related problems are of concern also, such as leakage of urine, sediment, and catheter related pain; yet it is unclear whether these problems contribute to blockage and CAUTI, and if so by how much. Catheter practices vary, such as catheter and balloon size and irrigation (Wilde et al. 2013), and it is not known whether any of these practices are associated with CAUTI and/or blockage of the catheter. The purpose of this paper is to report on a secondary data analysis from a randomized clinical trial (RCT) of 202 long-term indwelling urinary catheter users to explore these concerns and examine how the primary problems of CAUTI and blockage might be related and whether other factors contribute to them.

BACKGROUND

Long-term indwelling urinary catheters are used to treat urinary retention in people who either are not able to use an intermittent catheter (by self or with assistance) or manage getting to the toilet, e.g., related to limited mobility and/or disability. Occasionally catheters are used for incontinence. Most often people with long-term catheters are individuals with neurologic disorders, such as spinal cord injury or multiple sclerosis.

Exact prevalence of long-term indwelling catheter use is not known (Gould et al. 2009). However, in a report on incontinence in elderly persons in home care from the U.S. National Center for Health Statistics for years 2007–12, 9.1% were using a urinary catheter (13% of the men and 7% of the women). From the same report, at the end of life in hospice discharges, the percentage was higher, with 38% using a urinary catheter (38.8% of the men and 40.5% of the women; Gorina et al. 2014). However, surveillance estimates of CAUTI in home care populations usually combine short and long-term catheter users, such as in the Missouri Alliance for Home Care surveillance of CAUTI (MAHC 2011). Also, the U. S. Outcome and Assessment Information Set (OASIS) is used extensively in home care for Medicare/Medicaid tracking of outcomes and agency reimbursement, but identifying

catheter users is difficult because several types of catheters (e.g. intermittent or condom/sheaths) are subsumed in the single category of using a urinary catheter (Wilde et al. 2010).

Long-term catheter use is often for years, and small study samples indicate averages of 7.25 years (SD 9.25; Wilde, Dougherty 2006), 6.1 years (Kralik et al. 2007), and 11.7 years (median 8.8 years; Wilde et al. 2010). In the larger study of 202 catheter users from which the current study's data are derived, the mean was 6 years (SD 7 years; median 3.25 years; Wilde, McDonald et al. 2013).

CAUTI

CAUTI definitions recently have been modified to designate only *symptomatic* urinary tract infection in a person with a catheter (Gould et al. 2009). Essentially, every person using a catheter for over 30 days has been colonized, often with two to three types of microorganisms which change periodically (Warren et al. 1982). The National Healthcare Safety Network (NHSN) definition of CAUTI (http://www.cdc.gov/nhsn/enrolled-facilities/index.html) was developed for surveillance in agencies, including acute care settings, long-term care (nursing homes), and rehabilitation centers. Thus with these differences, criteria used for CAUTI diagnosis in acute care (Tambyah, Maki 2000) are not transferrable to chronic catheter users living in the community. For example, symptoms common in UTI in non-catheterized persons, such as frequency and urgency, are not as likely to signal CAUTI in those with a catheter (Wilde et al. 2013, Wilde et al. 2010). Risk factors for CAUTI include being female, older age and having more severe illness (Gould et al. 2009, Hooton et al. 2010). It is possible that kinks/twists or dependent loops in the tubing can contribute to CAUTI, but little evidence is available (Danek et al. 2015).

Blockage

Urinary sediment which causes encrustation and blockage of the catheter lumen is caused by the precipitation of calcium, phosphorus, and magnesium minerals in the urine in the presence of urea splitting microorganisms (Mathur et al. 2006), in particular *Proteus mirabilis* (Stickler, Feneley 2010) and *Providencia stuartii* (Kunin 1989). This process results in formation of a crystalline structure biofilm which protects the bacteria, making eradication of the biofilm very difficult. In the presence of such microorganisms, catheters can block within two days (Mathur et al. 2006), and all catheter materials seem to be colonized with this type of biofilm (Stickler, Morgan 2008). Although silicone catheters have been identified as possibly decreasing catheter blockage (Gould et al. 2009), more research is needed to determine the reason for this because silicone catheters have a larger internal lumen which facilitates urine flow.

Blockage of the catheter caused by sediment and encrustation within the lumen disrupts urine flow and can cause increased pressure within the bladder, which could contribute to pyelonephritis and septicemia (Stickler, Morgan 2008, Stickler 2008). While research in this area is very limited and not recent, the estimate of blockage in about 40–50% of long-time catheter users (Kunin 1989, Getliffe 1994) is often cited. Treatment of blockage is to change the catheter; other guidance is not available for long-term catheter users (Gould et al. 2009). Most clinical studies in long-term catheter users are of small samples and of short duration,

often a month or two at the most; therefore, the prevalence of blockage over longer periods of time is not known, nor are the factors known which contribute to blockage. Evidence in research to guide management or self-management of a catheter is lacking. For instance irrigation (also called flushing, washouts, or rinsing) is not recommended except in certain instances in acute care when bleeding is anticipated (Senese et al. 2006).

METHODS

Design

This is a secondary analysis of data from a randomized clinical trial (RCT) to determine whether catheter self-management could decrease catheter related problems (Wilde et al. 2015). The focus of the current study is to explore predictors of catheter problems, as well as to examine the relationship between CAUTI and blockage. Data are from six bimonthly interviews from the parent study which were conducted over 12 months (at months 2, 4, 6, 8, 10, and 12) in 998 interviews (N= 193) from 2009 to 2012. Seventy-five percent of the sample completed the full 12 months of the study. There were significant group differences only in the presence (yes/no) of blockage based on the bimonthly interview data during the first six months of the study, but not the frequency of blockage events. CAUTI outcomes did not differ by group. Importantly, both the experimental and control group improved in major outcomes of CAUTI and blockage during the 12 months of the study (Wilde et al. 2015). Therefore, data were used from the entire sample for the current analysis because our focus was on how CAUTI and blockage are related.

The aims of this study are to:

1. Describe the primary catheter problems (CAUTI, blockage) in persons using long-term indwelling urinary catheters; secondary catheter problems (e.g. sediment, catheter pain); catheter care practices (e.g., irrigation, catheter type and size); and excess health care utilization in treating CAUTI and blockage (e.g., excess nurse home visits, emergency department).
2. Explore the relationships of CAUTI and blockage in relation to demographics, secondary catheter problems and catheter care practices.

Sample and Setting of RCT (Parent Study)

Participants were community residing long-term indwelling urinary catheter users (N= 202) referred from two sites. Screening took place on the phone by the study coordinator or principal investigator at a university site in a northeastern U.S. state. The second site in a home care agency in a metropolitan area in the same state collaborated to recruit 75% of the sample; they used a data-base for screening to identify and exclude those with poor life expectancy or those with cognitive, behavioral, or hearing problems. Participants were included in the study if they expected to use an indwelling urinary catheter for at least a year, had access to a phone for interviews, and planned to live in the region for at least four months (during the intervention time frame). Human subjects' approval was obtained at both sites and full written informed consent was acquired for each participant during the initial home face to face interview.

Intervention

The intervention (experimental) group received three home visits (HV) by trained study nurses, two HVs in the first month, a phone call two weeks later, and a final HV at four months. The purpose of the visits was to teach self-management of the catheter, with a focus on optimal fluid intake and preventing accidental catheter dislodgment. Study nurses used a 3-day urinary diary and a 20 page educational booklet (related to catheter problems and possible strategies) for individualized teaching. Goals were set, reassessed over time and adjusted as needed. See (Wilde, Zhang et al. 2013) for further details. The control group received only their usual catheter care through home care agencies and/or visits with providers in clinics or medical offices.

Instruments

Three instruments related to demographics, catheter care, and catheter problems had been developed originally for two preliminary studies (Wilde, Dougherty 2006), including the pilot study (Wilde, Brasch 2008), and modified further for the parent RCT (Wilde et al. 2015). The *Demographics Questionnaire* was used to describe the sample at the beginning of the study, e.g., age, sex, race/ethnicity, activities of daily living, and medical diagnosis. The *Catheter Care Questionnaire* was used to collect data about catheter care practices for example, catheter type (urethral/suprapubic), size of catheter and balloon, and irrigation practices. The *Catheter Problems Questionnaire* was used to identify primary outcomes of CAUTI and blockage as well as secondary catheter problems for our analysis such as leakage, kinks/twists, bladder spasms, catheter pain, sediment, and dislodgment. Frequency and details about these problems were also asked, including several items to identify excess health care utilization related to CAUTI or blockage, like nurse home visits or emergency department visits. For blockage, treatments for only the first 12 of the events were reported within each bi-monthly assessment.

Initial content validity for the *Demographics and Catheter Problems Questionnaires* were scored by three internationally known researchers. 94% of the items were rated as highly relevant and succinct and 6% were relevant but needed minor revision, which was done. CAUTI was defined as a urinary tract infection which had been diagnosed and treated with an antibiotic. Blockage was defined as a time when the urine would not flow within the catheter (as compared with something external like a kink or twist). The *Catheter Care Questionnaire* also was evaluated for content validity by the same reviewers. One percent of the items was scored as needing serious revision and were removed or modified; 14% were rated as requiring revisions which were made; and 85% were rated as requiring no change.

Procedure

As indicated above, we used secondary data collected from the parent RCT (Wilde et al. 2015). The demographics and catheter care initial baseline data were collected during a face to face home interview prior to randomization at the beginning of the study. For the current study period, data were collected bimonthly (months 2–12) through phone call interviews with a trained interviewer that captured catheter related events that occurred within this 2 month window. To aid recall, a 12 month catheter calendar had been given to all study participants (experimental and control) to remind them during phone interviews about the

number and dates of the primary catheter problems. The calendar had a brief code for problems (U for CAUTI, B for blockage, and D for dislodgement) and treatments (HV for extra nurse home visit, O for office visit, A for antibiotic, ER for emergency room, H for hospitalization, and R for rehabilitation). While dislodgement was a primary outcome in the parent study, for the current analysis it was considered secondary. No calendar was used for the face to face initial baseline interview, strictly relying on recall over the previous two months' time.

Questions related to catheter practices and secondary problems were asked also every two months through recall only. Study participants were asked yes/no questions about whether a catheter problem had occurred during the previous two month period, and then follow up questions were asked depending on the answer. For blockage, participants also were asked whether the catheter was changed or irrigated, and follow-up questions were asked only about the first 12 events during each interview. Likewise, participants were questioned about catheter care practices every two months, such as the size of the catheter, whether they had irrigated the catheter, etc.

Measurement

Blockage and CAUTI—The number of blockages and CAUTI occurring from baseline through 12 months' follow up were computed from data from bi-monthly phone interviews. Extreme blockage values (outliers) were winsorized at 9 within each two month data collection period. For CAUTIs, however, there were no instances of extreme values in the data. Counts of blockage and CAUTI were computed for a participant who had at least one event across the six data collection points by computing an average of the present counts and multiplying by 6. Mean imputation was used to account for missing data over the six bi-monthly data collection points.

Urinary sediment amount—A single urinary sediment amount score was computed by taking the average amount of sediment reported: 0 = None; 1 = Small amount (hardly noticeable); 2 = Moderate amount (can see in tubing and bag if looking for it); 3 = Large amount (very easy to see in tubing and bag) across the six measurement periods.

Catheter leakage and bladder spasm frequency—Frequency scores were recoded within each two month data collection point to provide a total count estimate across the 12 month time period. The original frequency responses were recoded using the following estimates: 0 = 0 "No sediment in past 2 months"; 1 = 1 "Once in past 2 months"; 2 = 2 "Once a month in past 2 months"; 3 = 5 "Several times a month in past 2 months"; 4 = 8.7 "Once a week for past 2 months" (4.35 weeks in a month); 5 = 21.75 "Several times a week for past 2 months"; 6 = 60.88 "Daily for past 2 months" (30.44 days per month). Total leakage and bladder spasm frequency counts were computed for a participant who had at least one leakage score across the six data collection points by computing an average of the counts and multiplying by 6.

Higher levels of disability—A measure of disability was used from the Katz instrument (Katz et al., 1963) of independence in activities of daily living assessing whether the person is dependent on another person for help with feeding self.

Data Analysis

Data were collected via an electronic platform (Audio Computer Assisted Self-Interview) and sent to the data analyst at the University site for cleaning and verification prior to analysis. Variables of interest for this secondary analysis were identified for theoretical relevance to CAUTI and/or blockage. The prevalence of primary catheter related problems were identified for the 12 months of the study (i.e., for interviews at months 2, 4, 6, 8, 10, 12), and rates per 1000 catheter days were calculated (event frequency/days of catheter use × 1000). Baseline data in conjunction with 6 and 12 months' data were used to describe the sample related to catheter practices and to determine whether there were changes over time (Aim 1). One person's data were removed for blockage only due to inconsistent responses (i.e., not always answering based on our definition of blockage); therefore, the sample for analyses during the study period *after baseline* was 193 for CAUTI outcomes and 192 for blockage. These data were used for the exploratory analysis using logistic regressions and the multi-variate analysis testing associations of predictors on the primary outcomes of CAUTI and blockage (Aim 2). The number of participants varied over time, and some follow up questions were not asked if they did not pertain; therefore, the Ns are reported in the tables.

Descriptive data were analyzed for frequencies, central tendency, spread, and outliers, using SPSS ver.23 (IBM Statistical Program for Social Sciences, Carey, NC). To identify predictors of the main outcomes of CAUTI and blockage, generalized estimating equation (GEE) models were used for the logistic regression analyses in order to adjust for the hierarchical structure (i.e., repeated observations) in the data. Multiple regressions were conducted to explore the relationships between theoretically relevant predictor variables and outcomes. To handle the excess zeroes in the data in CAUTI and blockage outcomes–meaning these events did not occur in a substantial number of the subjects–zero inflated negative binomial (ZINB) models (Atkins, Gallop 2007) were analyzed, one for each dependent variable using robust maximum likelihood estimation with the MPlus statistical software program (Muthen, Muthen, 2012). A zero-inflated negative binomial regression is a mixture model in which the distribution of the outcome is approximated by mixing two component distributions. Here, we assume a logistic model for the "zero, not zero" aspect of the model and a negative binomial distribution to account for the over-dispersion of variance for the counts portion of the model (standard deviation greater than the mean for count variables). Thus, there are two sets of coefficients for ZINB models relating to the logistic and counts portions of the models.

RESULTS

Rates per 1000 catheter use days and measures of central tendency for CAUTI, blockage, and dislodgement over the study period (months 2–12) are depicted in Table 1. Relationships between variables believed to predict CAUTI and blockage outcomes are shown in Table 2.

Table 3 compares catheter care practices at baseline, 6 and 12 months. Table 4 shows the frequencies of excess health care utilization for each of CAUTI and blockage for months 2–12. Table 5 reports the correlations of variables used in the ZINB regression model testing, and Table 6 depicts the model results for outcomes of CAUTI and blockage.

Participants

The sample at baseline included 52% male from 19–96 years (median age 61), with a wide range of race: 57% white; 30% black; 2% each Asian, American Indian or Alaskan Native, or biracial; and race was not known for 9%. Hispanic was identified by 11%. Sixty percent needed help with most activities of daily living of: toileting, getting out of bed, bathing, and dressing. An additional 19% needed help in feeding self. The most common medical diagnoses, which were self-reported and related to why the person had the catheter, were: spinal cord injury (40%), multiple sclerosis (23%), diabetes (12%), and prostate disease (10%). Other diagnoses included: Parkinson's disease (2%), stroke (2%), spina bifida (1%), and other neurogenic bladder diagnoses not otherwise reported (8%). 56% used a urethral catheter (UR), 44% used a suprapubic (SP), and 1% used both. A full description of the sample is available elsewhere (Wilde et al. 2013).

Catheter Types and Sizes

Catheter type (UR or SP), catheter size, and balloon size were not significantly associated with CAUTI or blockage (Table 2). There was a slight shift in more participants using SP catheters over time: 44.1% at baseline, 46% at 6 months, and 48% at 12 months (Table 3).

Catheter size was reported every two months in units French (Fr), which measures the external diameter and is the same as Charrière (Ch). Both catheter and balloon sizes changed little during the study (see Table 3). Sizes at baseline were most often 16Fr or 18Fr, but there was an increase in larger size catheters over the study period. Balloon sizes were mostly in the 5–10mL range. Of the 35 subjects who had reported 30 mL balloons, none reported that their catheter balloon sizes decreased during the study. In addition, at baseline, 6 and 12 months, some individuals (7–8%) did not know their catheter size. Balloon size was not known by a larger number (21–23%).

CAUTI and Blockage (Tables 1 & 2)

Rates per 1000 catheter days' use are shown in Table 1. CAUTI occurred at least once in 57% of the sample (n= 110) for a total of 268 events during the 12 months of the study, and a range of 1–11 events per person in those with CAUTI. For blockage, there was a wide variation in number of blockages (frequencies) reported. There were 507 reports of blockage in 34% of the study participants (n=66) during the 12 month study, with a range of 1 to 180. As noted in the legend in Table 1, 87% of the bi-monthly responses to whether they had any blockage were negative. Catheter blockage was *marginally significant in* predicting CAUTI, with an odds ratio of 1.52 (CI= 0.99, 2.33) P=.057 (Table 2).

Dislodgement (Accidental Pulling Out of the Catheter)

Dislodgement was reported much less frequently than CAUTI or blockage. It occurred in 85 people (28% at least once) for a total frequency of 139 during the 12 months of the study, with a range of 1–10 events. Dislodgement was not related to blockage or CAUTI, Table 2.

Secondary Catheter Problems (Associations by Logistic Regressions, Table 2)

Leakage was reported at least once by 68% of the sample during the 12 months, and it was significantly related to blockage and CAUTI (Table 2). Kinks/twists in the catheter were reported at least once by 42% of the sample, but were not related to blockage or CAUTI. Bladder spasms were reported by 59% of the sample, and they were significantly related to CAUTI and blockage. Catheter related pain was reported by 49% of the sample at least once during the full 12 months of the study, but it was not significantly related to CAUTI or to catheter blockage. Pain was reported between 21–24% of the sample (Table 3). Of those who had catheter pain, reasons for it varied by person and by time point interviewed, including some with catheter changes and a few had catheter pain *all the time.*

Sediment was reported by 87% of sample at least once, and it was significantly associated with both blockage and CAUTI. The odds of having blockage (but not CAUTI) increased with more frequent episodes of sediment and with larger amounts of sediment (Table 2). However, persons with *large* amounts of sediment also were more likely to report CAUTI. In general, sediment amounts decreased during the study period from baseline to 12 months, but there were no discernable changes in the frequency of sediment (Table 3).

Difficulty with Insertion/Removal of the Catheter (Table 3)—Difficulty in inserting or removing the catheter was reported at least once by 38% of the sample. The percentage reporting this decreased somewhat from 17% at baseline to 13% at 12 months, and the great majority reported this happening once or twice. The most challenging events were during insertion as compared with removal. For the difficulty rating, individuals were asked to rate their most difficult experience with insertion or removal, using a scale from 1–10 with 1 meaning “just a little more difficult than usual” and 10 with being “a highly challenging situation.” A large percentage rated their most difficult event as between 8 and 10. (Table 3)

Irrigation

Catheter irrigation was reported by 67% percent of the sample. While irrigation was significantly related to blockage (OR 3.67; 2.13, 6.33; P= <0.001) and not CAUTI, no real clear pattern of association was identified between the frequency of irrigation and CAUTI or blockage. Irrigation was done for prevention, when treating a catheter problem like sluggish or blocked urine flow, or for both prevention and treating a problem. The relationships between irrigating for prevention and problems or just for problems were significantly associated with both CAUTI and blockage. (Table 2)

Irrigation solutions comparing baseline, 6 and 12 months indicate that the solutions used by participants did not change much over time (Table 3). Some persons reported use of more than one solution, and the great majority used saline, followed by sterile water, then tap water, and a few used Renacidin® (Generic name and formulation: Citric acid 6.602g,

glucono-delta-lactone 198mg, magnesium carbonate 3.177g; per 100mL; irrigation soln (pH 3.85; http://www.empr.com/renacidin-irrigation/drug/3154/.

Health Care Utilization related to Treatments for CAUTI and Blockage (Table 4)

Compiling data related to treatments asked for each episode of CAUTI and blockage indicates that a large percentage of catheter problems are managed by additional healthcare utilization. For CAUTI events, we had full information for treatments; however, for blockage events, since we had capped those events at 12 for each time-point, we present information in Table 4 only on the number and percentage of people who had blockage at least once in the 12 months' study. Therefore, blockage data were related to having had the treatment at least once during the study.

Multivariate Regression Model Findings

We used the results from the bi-variate logistic regressions (Table 2) to conduct the multivariate regression model testing. Age and gender have been identified as risk factors for CAUTI and thus included in the model (Maki, Tambyah 2001). Kinks/twists in the catheter, catheter pain, and the type and size of the catheter had been believed to contribute to the outcomes of CAUTI and/or blockage, but our logistic regressions indicated that they were not; thus those variables were not included in the 12-month model. Irrigation is a treatment, not a problem; therefore, while our data reflect practices related to CAUTI and blockage, the irrigation variables were not considered appropriate for testing associations with outcomes. ADL5 represents people who need assistance with feeding and could require more help with managing the catheter, e.g., irrigations and/or catheter changes; thus ADL5 was included in the models. Sediment amount was considered more important than the frequency of sediment in predicting blockage and/or CAUTI; thus the amount of sediment was included in the model testing while frequency was not.

Table 5 present the means, standard deviations, and correlations among the regression model variables. As noted in Table 5, blockage and CAUTIs were modestly correlated (.35, $p < .001$). Univariate analysis suggests that urinary sediment amount and bladder spasms are both related to the number of blockages and CAUTIs. Examination of Table 5 also suggests that over dispersion exists in both of the CAUTI and blockage dependent variable rates, as the standard deviations exceed the mean in both instances. For these participants, over 43% of the sample had no CAUTI's over the twelve-month period and over 66% had no blockage.

Table 6 presents results of the zero inflated negative binomial model predicting CAUTI and blockage. For CAUTIs, no variables significantly predicted the presence/absence of CAUTI. For the counts (frequencies) of CAUTIs, the number of bladder spasms was significantly related to the count of CAUTIs (B = .003, p = .044), as bladder spasms increased, so did the number of CAUTIs. Additionally, both urinary sediment amount (B = .204, p = .055) and number of catheter leakages (B = .002, p = .074) were both positive and marginally significant. As both sediment amount and catheter leakages increased, so did the count of CAUTIs.

For blockage, both the amount of urinary sediment (B = −1.605, p = .026) and number of catheter leakages (B = .014, p = .032) significantly predicted the presence/absence of

blockage in the year. Surprisingly however, larger sediment amounts were associated with a lower probability of reporting any blockage in this time period. For catheter leakages, more leakage was associated with a higher probability of reporting blockage. For blockage counts (frequencies), being female was associated with less blockages (B = −1.486, p < .001). Higher urinary sediment amount was associated with more blockage (B = 1.019, p < .001) and a higher number of catheter leakages was also associated with more blockage (B = .016, p = .002). Additionally, the presence of eating problems was marginally significantly associated with more blockages (B = 1.013, p = .054). Thus, while higher levels of sediment amount lower the probability for any blockage, higher levels of sediment amount is associated with higher levels of blockages for those who report some blockage.

DISCUSSION

This study was an in depth examination of how CAUTI and catheter blockage are associated and how these variables are associated with other theoretically relevant variables. Analysis of this sort on a large scale had not been done before. Although the relationship of CAUTI and blockage was found to be only *marginally related* (OR 1.52, 95% CI 0.99,2.33; P= 0.057) throughout the study period, other variables examined suggest how these catheter problems are related and suggest further exploration of relationships. While significant associations of CAUTI and blockage were reported in the parent study at baseline (N=202) (Wilde et al. 2013) and in two small samples (N= 24 and 30 respectively), (Wilde, Carrigan 2003; Wilde, Dougherty, 2006), this relationship had not been reported in a large and more diverse sample. The repeated measures used in this study also shed light on how catheter problems occur over time and how much variability exists among catheter users, particularly related to blockages. Clearly there is no one pattern of catheter problems. Rather, key problems seem to be related to one another–specifically CAUTI, blockage, sediment, leakage, bladder spasms, and pain–but not all of the problems are related to both CAUTI and blockage, nor in the same individuals. More longitudinal research targeting people with *frequent blockage* is needed to better understand some of the relevant issues. While a norm of what constitutes “frequent” has not been determined, researchers identified a frequency of catheter changes more than twice in an 18 week period as “frequent,” given routine changes of every six weeks (Getliffe 1994).

The large number of observations over time in this highly diverse sample increases the value of these findings. Also, secondary catheter problems (e.g., sediment, leakage, pain) were not considered in the main findings (parent study) analysis of group differences, and these problems are reported in detail here for the entire sample.

CAUTI and Blockage Association with Other Factors (Table 2)

Relationships with CAUTI were found not only for blockage but also for leakage, bladder spasms, sediment and irrigation for prevention/problems. These associations could point to an inherent relationship between CAUTI and blockage, which is theoretically logical because blockage can contribute to injury to the bladder and/or kidneys due to ureteric reflux from high bladder pressure, and bladder spasms can exacerbate the problem (Feneley, Hopley & Wells 2015). Surprisingly, neither CAUTI nor blockage outcomes were related to

catheter type (UR or SP), size, or balloon size, nor to kinks/twists in the catheter, each of which could contribute to CAUTI from diminished blood flow to the bladder mucosa.

Some people were affected by repeated blockages, and others had blockage rarely. It is often reported in the literature that blockage affects about 40–50% of the long-term catheter users population who are commonly referred to as “blockers” as compared with “non-blockers” (Kunin, Chin & Chambers 1987, Getliffe 2002). Our sample reflected a smaller percentage with blockage (i.e., 34% who had it at least once), but our report is closer to the estimate in a meta-analysis report in which the pooled estimate of blockage in outpatients was 28.7% (CI 8.8–71.1%) (Hollingsworth et al. 2013).

Catheter Related Pain, Difficulty with Insertion/Removal, and Bladder Spasms (Table 3)

While this study provides some information about catheter related pain, insertion/removal issues, and catheter related bladder spasms, clearly more research is needed. The catheter itself was a common source of pain affecting almost half the sample. Some pain could be minimized by positioning it better so that the person is not sitting directly on it, assuring use of any prescribed anti-spasmodic medication for those with persistent bladder spasms, and by using an anesthetic gel for insertion. People with persistent pain should be evaluated for latex sensitivity and for whether the catheter is properly anchored to prevent traction.

Catheter insertion or removal, particularly insertion, was problematic for more than a third of the sample at some time during the study. Most related literature is based on case series, such as trauma resulting from incorrect catheter insertion in males, often related to prostate obstruction (Villanueva, Hemstreet 2008, D’Cruz et al. 2009) or about techniques for removal of a non-deflating catheter balloon (Patterson et al. 2006). Information about patients’ responses to catheter changes is lacking, as well as exploration of complex relationships among variables like neurogenic bladder, bodily spasticity, sensation in the bladder, length of time using a catheter, latex allergy, medications, and use of anesthetic gels on insertion.

The reason for bladder spasms (in the logistic regressions, Table 2) being related to both CAUTI and blockage is not clear. Clearly some catheter users with neurogenic bladder are prone to bladder or bodily spasms. The bladder could be more irritable with recent infection or when urine is flowing poorly; thus bladder spasms could be an early warning signal in people who do not have them frequently.

Catheter Characteristics (Table 3)

Larger size catheters of over 18 Fr increased during the study from baseline at 30.8% of the sample to 40.4% at 12 months. This finding was surprising, given that smaller sized catheters are recommended (Cottenden et al. 2013, Parker et al. 2009, WOCN Society Clinical Practice Continence subcommittee 2009). Besides increasing size to manage sediment and/or blockage, some nurses may still believe that “plugging the leak” with a larger diameter will help decrease urine leakage, when it is clear that increasing the size is more likely to irritate the bladder sphincter and worsen leakage (Switters 1989). Balloons of 30mL size were designed for post-operative bleeding control; therefore the fact that 14–19% of the sample had large balloons is of interest.

Sediment and Irrigation of Catheters (Washouts)

In the United Kingdom catheter maintenance solutions, Suby R or Suby G instillations (sold in sachets) are used to dissolve encrustations when catheter change is not appropriate (Getliffe 2003), but these solutions are not available in the U.S. and irrigation is not recommended (Gould et al. 2009). In Canada in one RCT with three arms and eight weeks of observation, irrigation (called washouts) using saline, a buffered sachet of an acetic solution, or no irrigation did not extend the time to catheter changes. The authors concluded that the study was underpowered with 73 enrolled and 53 completers (Moore et al. 2009). Nevertheless, it is clear from our data that people do irrigate to manage encrustation and blockage, and that the blockage is caused by sediment. It is striking to see that a full 87% of our sample reported sediment at least once during the study.

In our study, people used saline or water most often for catheter irrigation, (92–99%) (Table 3). Tap water use for irrigation by 5–9% is of concern because it is not guaranteed to be free of micro-organisms and no guidelines suggest its use. Renacidin® (used by 4–5%) is an acetic solution ordinarily used for dissolving renal stones, and it can be effective in dissolving the crystalline substance of the biofilm; however, it can be irritating and must be obtained directly from a pharmacy. A new catheter irrigation solution was tested in vitro with encouraging results (Rani et al. 2015); however, further testing is needed in clinical trials.

Eliminating *P mirabilis*, through aggressive treatment in persons recently infected with that microorganism, could prevent catheter blockage in some individuals (Stickler, Feneley 2010). However in those already chronically colonized, increased fluid intake to offset the pH nucleation point (i.e., precipitation pH which causes the sediment to drop into urine) through more dilute urine could help decrease blockage (Khan et al. 2010). Additional evidence comes from our research teams' structural equation model testing in which fluid intake was significantly associated with decreased blockage frequency in the full sample (Wilde et al. 2016).

Excess Healthcare Utilization Related to CAUTI and Blockage

Very little research has been done prior to the current study about the extent of excess healthcare utilization for CAUTI and/or for blockage. Our research team had reported data previously on excess healthcare utilization over a two months' period at baseline (N=202), but no calendar was used to aid memory (Wilde et al. 2013). Undoubtedly some individuals/caregivers are able to address catheter blockage by irrigation or changing the catheter. Disproportionately large costs by a small number of people with problems were reported also in a community study in England (Evans et al. 2000) and in nursing home residents in Sweden (Jonsson, Hedelin 2013).

Regressions Model Analysis

Few studies have identified factors associated with CAUTI and/or blockage, and none that we know involve persons in community settings with long-term catheter use. This study provides information not reported before that sediment and catheter leakage were associated with blockage and that bladder spasms were associated with CAUTI.

Limitations

Several limitations exist for this study. We did not collect information for a true cost analysis with billing and diagnostic codes, and this would be of benefit to facilitate more cost effective care management strategies. For instance, knowing the reasons for catheters being changed in the emergency department could lead to interventions to prevent unnecessary expense. Also, while we asked only about treatments related to the first 12 catheter blockages, the calendar recordings provided a level of presumed accuracy. Nevertheless, we did not collect data on the *true frequency* of excess healthcare utilization related to blockage events. Finally, all outcomes were self-reported and identification of CAUTI was a patient report of a physician diagnosis and treatment for CAUTI. With the multiple referral sources it was not possible to obtain urine cultures or to determine criteria used by providers in diagnosis of CAUTI.

CONCLUSION AND RELEVANCE TO CLINICAL PRACTICE

This large and diverse sample provides a first time longitudinal view of episodes of CAUTI and blockage in persons using long-term indwelling urinary catheters, how these problems are related, and how they are associated with other factors. More research is needed to better determine patient reported patterns of catheter problems through use of written diaries or electronic data collection. Knowing which symptoms signal catheter problems which require intervention and which are rather benign would be of tremendous practical importance. Prospective microbiological studies, a full cost analysis study, and trials of catheter maintenance solutions are indicated. Obtaining large samples for such research is challenging (Fairbanks et al. 2014) and it likely would require multiple sites research.

Clinicians could better identify catheter problems by tracking them systematically with their patients. Knowing the patient’s patterns of catheter problems could inform care strategies, such as recognizing when the catheter is likely to block to schedule pre-emptive changes, or for searching for ways to decrease catheter pain and/or bladder spasms.

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What does this paper contribute to the wider global clinical community?

- Long-term indwelling urinary catheter users often experience catheter-related problems which differ in type and frequency among individuals using the device.
- Catheter-related urinary tract infection (CAUTI) is marginally related to catheter blockage.
- Both CAUTI and blockage contribute to excess health care utilization.
- Sediment and catheter leakage were associated with blockage and bladder spasms were associated with CAUTI.

Table 1

Descriptive statistics and rates for primary catheter problems over a 12 month period

Primary catheter problems (# events)	Percentage reporting problem*	Mean (SE)	Rate/1000 catheter days
CAUTI (268)	57%	0.27 (0.017)	4.49
Blockage (507)	34%	0.51 (0.114)**	8.54
Dislodgement (139)	28%	0.14 (0.019)	2.33

*Indicates the percentage of study participants who had this happen ***at any time*** during the previous 12 months, rounded to nearest percent. This does not include baseline data.

**Zero-inflated count variable: 87% of responses were zero. Among non-zero responses bi-monthly, the range was 1 to 60, mode and median=1, mean=3.96 (SE: 0.81), 5% trimmed mean=2.28 (SE: 0.34).

Table 2

Effect size estimates for predictors of CAUTI and blockage

	CAUTI		Blockage	
Variable	**OR (95% CI)**	**P-value**	**OR (95% CI)**	**P-value**
Blockage	1.52 (0.99, 2.33)	0.057		
Catheter problems (secondary)				
Leakage (yes/no)	1.34 (1.00, 1.79)	0.052	1.91 (1.19, 3.04)	0.007
Kinks/twists (yes/no)	1.15 (0.82, 1.61)	0.418	1.40 (0.83, 2.35)	0.203
Bladder spasms (yes/no)	2.86 (2.00, 4.08)	>0.001	1.62 (1.06, 2.47)	0.026
Catheter related pain (yes/no)	1.00 (0.97, 1.05)	0.720	1.13 (0.70, 1.83)	0.609
Sediment (yes/no)	1.81 (1.28, 2.55)	0.001	4.23 (2.45, 7.28)	<0.001
Sediment frequency [a]				
Daily	1.04 (0.63, 1.71)	0.888	3.39 (1.60, 7.18)	0.001
Several times a week	0.78 (0.46, 1.32)	0.344	1.98 (0.96, 4.11)	0.066
Once a week	0.82 (0.44, 1.55)	0.550	1.23 (0.56, 2.73)	0.605
Several times a month	1.00 (0.66, 1.51)	0.998	2.11 (1.07, 4.14)	0.031
Once a month or less	Reference		Reference	
Sediment amount [a]				
Large	2.78 (1.71, 4.50)	>0.001	2.91 (1.54, 5.50)	>0.001
Medium	1.05 (0.71, 1.54)	0.815	1.91 (1.16, 3.12)	0.01
Small	Reference			
Dislodgement (yes/no)	0.64 (0.36, 1.15)	0.134	1.36 (0.75, 2.46)	0.317
Characteristics & catheter care				
Type of catheter				
Suprapubic	0.93 (0.61, 1.40)	0.711	1.68 (0.94, 3.02)	0.082

	CAUTI		Blockage	
Variable	**OR (95% CI)**	**P-value**	**OR (95% CI)**	**P-value**
Urethral	Reference			
Catheter size [b]	1.01 (0.96, 10.7)	0.674	1.06 (0.99, 1.13)	0.105
Balloon Size [c]				
5–10 cc	1.28 (0.78, 2.16)	0.356	1.18 (0.62, 2.24)	0.613
30 cc	Reference			
Irrigation (yes/no)	0.96 (0.70, 1.32)	0.807	3.67 (2.13, 6.33)	<0.001
Irrigation frequency [d]				
Daily or several times a day	0.76 (0.35, 1.65)	0.490	2.72 (1.06, 6.99)	0.037
Several times a week	1.41 (0.51, 3.90)	0.505	1.30 (0.46, 3.69)	0.625
Once a week	0.85 (0.35, 2.06)	0.720	2.02 (0.72, 5.71)	0.183
Several times a month	0.54 (0.24, 1.23)	0.139	1.34 (0.57, 3.15)	0.500
Once a month	0.42 (0.19, 0.94)	0.034	0.70 (0.31, 1.54)	0.370
Once in past two months	Reference			
Irrigation for prevention [d]				
Prevention and problems	1.88 (1.07, 3.29)	0.027	3.80 (2.12, 6.79)	>0.001
Problems only	2.07 (1.24, 3.47)	0.006	3.55 (1.76, 7.17)	>0.001
Prevention only	Reference			

Only subjects reporting the problem or treatment:

[a]: n=165;

[b]: n=188;

[c]: n=166;

[d]: n=128

Table 3

Catheter characteristics table (reported in valid percentages)

Catheters	**Baseline %**	**6 months %**	**12 months %**
Catheter type	n=202	n=161	n=150
Urethral	55.4	53.4	51.3
Suprapubic	44.1	46	48
Both	0.5	0.6	0.7
Catheter size	n=185	n=145	n= 136
<18 (to 6 Fr)	38.9	32.4	32.4
18 Fr	30.3	30.3	27.2
>18 (to 40 Fr)	30.8	37.2	40.4
No catheter size change in 2 months	NA	n= 158 89.9	n= 149 89.3
Balloon size	n=155	n=118	n=106
5–10 mL	80.0	82. 2	84.0
30 mL	18.8	13.6	16.0
Other	1.3	4.2	0
No balloon size change in 2months	NA	n=146 95.5	n= 141 97.9
Sediment, Irrigation	Baseline %	6 months %	12 months %
Sediment amount checked	n=126	n=99	n=85
Small	41.3	40.4	47.1
Medium	34.1	42.4	36.5
Large	24.6	17.2	16.5
Sediment frequency	n= 126	n=99	n=85
Daily	23.8	20.2	24.7
Once –several times week	29.3	31.3	34.1
Once-several times a month	39.7	42.4	38.8
Once in two months	7.1	6.1	2.4
Irrigation solutions	n=71	n=57	n=61
Saline	76.1	77.2	85.2
Sterile water	22.5	12.3	6.5
Tap water	8.5	8.7	4.9
Renacidin®	4.2	5.3	4.9
Difficulty & pain	Baseline %	6 months %	12 months %
Difficulty in insertions or removal	n=35	n=28	n=19
Occurred once or twice in two months	88.6	85.7	94.7
Insertion, as compared with withdrawal	68.6	53.6	61.1

Catheters	**Baseline %**	**6 months %**	**12 months %**
Difficulty rating of 8–10 (out of 1–10)	54.3	50.0	44.4
Catheter pain related to:	n=46	n=33	n=36
Positioning	45.7	36.4	33.3
Bladder spasms	45.7	36.4	58.3
Some catheter changes	30.4	12.1	19.4
Each catheter change	26.1	33.3	22.2
All the time	13	24	17
How much catheter-related pain bothers:	n=46	n=33	n=36
Not at all	0	3.0	2.8
Very little	15.2	15.2	38.9
Somewhat	45.7	45.5	27.8
A great deal	39.1	36.4	30.6

* The percentages are reported in valid percentages only *for those who had the problem*.

NA= This was not applicable as this item was not asked at the baseline interview

Table 4

Excess healthcare utilization reported

Treatments for	**CAUTI**		**Blockage**	
Type of excess healthcare events	**Total n events (n=268)**	**Number and % people affected (n=110) (57%)**	**Total n events for reports on up to 12 blockages (n= 344)**	**Number and % affected people affected (n=66) (34%)**
Extra nurse home visit	50	40 (36.70%)	97	26 (39.39%)
Extra office visit	73	45 (41.28%)	29	18 (27.27%)
ED visit	79	51 (46.79%)	17	12 (18.18%)
Hospitalized	49	31 (28.44%)	N/A	N/A
Catheter changed	155	84 (77.06%)	209	55 (83.33%)
Urine cultured	216	98 (89.91%)	N/A	N/A
Antibiotic prescribed	267	109 (100%)	N/A	N/A

Table 5

Sample size, means, standard deviations and correlations among study variables.

		N	*Mean*	*SD*	1.	2.	3.	4.	5.	6.	7.	8.
1.	Gender	193	1.49	.50	1.00							
2.	Age	193	61.23	17.54	−.03	1.00						
3.	Requires help with eating	193	.18	.38	.06	−.25***	1.00					
4.	Average urinary sediment amount	193	1.07	.78	.08	−.29***	.14*	1.00				
5.	Number of catheter leakages	193	26.48	55.48	.10	−.02	−.07	.12	1.00			
6.	Number of bladder spasms	193	48.82	89.65	.06	−.22**	−.03	.14[a]	.22**	1.00		
7.	Number of UTIs	193	1.67	2.26	.05	−.15*	.09	.33***	.07	.36***	1.00	
8.	Number of blockages	192	2.28	6.87	−.09	−.09	.05	.32***	.09	.18*	.35***	1.00

Notes:

*** $p < .001$,

** $p < .01$,

* $p < .05$,

[a] $p < .10$.

SD=standard deviation.

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Table 6

Summary of Zero-Inflated Negative Binomial (ZINB) Regression Predicting Catheter Associated Urinary Tract Infections (CAUTIs) and Blockages.

	Catheter Associated Urinary Tract Infection (CAUTI; *n* = 193)				Blockage (*n* = 192)			
Variable	***B***	***SE B***	***Z***	***p***	***B***	***SE B***	***Z***	***p***
Logistic portion of model (Yes/No)								
Intercept	.266	1.701	.157	.876	1.348	3.190	.423	.673
Gender	−1.228	1.207	−1.018	.309	−2.143	1.659	−1.292	.196
Age	.013	.034	.366	.714	.012	.028	.434	.665
Eating Problem	−.398	1.747	−.228	.820	1.814	1.471	1.233	.218
Urinary Sediment Amount	−.310	.836	−.371	.710	−1.605	.720	−2.230	.026
Count of Catheter Leakages	.007	.005	1.286	.198	.014	.007	2.144	.032
Count of Bladder Spasms	−.003	.006	−.563	.573	.006	.005	1.253	.210
Counts portion of model (frequencies of events)								
Intercept	.323	.555	.582	.560	.505	1.294	.390	.697
Gender	−.224	.189	−1.183	.237	−1.486	.374	−3.974	< .001
Age	.001	.010	.107	.915	.006	.011	.516	.606
Eating Problem	.220	.328	.671	.502	1.013	.525	1.928	.054
Urinary Sediment Amount	.391	.204	1.916	.055	1.019	.279	3.657	< .001
Catheter Leakages	.002	.001	1.790	.074	.016	.005	3.136	.002
Bladder Spasms	.003	.001	2.017	.044	.003	.002	1.469	.142
Residual Dispersion	.314	.297	1.057	.290	2.426	.591	4.105	< .001

Note: Gender (1 = male; 2 = female); Eating Problem (0 = no; 1 = yes).