

A RANDOMIZED CLINICAL TRIAL OF SELF-MANAGEMENT OF URINE FLOW IN LONG-TERM INDWELLING URINARY CATHETER USERS

Hypothesis / aims of study

The study was designed to determine whether a urinary catheter self-management intervention could decrease catheter-associated urinary tract infection (CAUTI), catheter blockage, associated healthcare costs, and improve catheter-related quality of life.

Study design, materials and methods

The study was a randomized single blinded parallel group experimental design in New York State, USA, with repeated measures over a 12 month period. Community living long-term indwelling urinary catheter users over the age of 18, who could complete study measurements, speak English, and have access to a telephone were randomly assigned to either the experimental self-management group or control group receiving usual care. Individuals were excluded for terminal illness, cognitive impairments, or not having had CAUTI within the last year, or blockage within the last six months. In the experimental group, catheter users had three home visits (HV) with a study nurse in months 1, 2, and 4 to teach awareness and self-monitoring of patterns of urine flow and to how to modify self-management behaviour as needed. The education focused on teaching related to drinking optimal and consistent levels of fluids of decrease blockage [1] and to prevent catheter dislodgment. Both groups tracked catheter problems with a simple calendar for use in the self-reported data collection through bimonthly phone call interviews. Block randomization was stratified by site to balance the large number of study subjects in the metropolitan site (75% of participants) as compared with the university site which is a mixed urban/rural setting (25% of participants). Using sealed envelopes, subjects were sequentially assigned to group after completing the consent and initial HV interview with a trained data collector. Study investigators, data gathering teams, and statisticians were blinded to allocation status until the final analyses were completed. Power was calculated a priori at 80% for a significance level of .05 for a medium effect size in primary outcomes, recognizing that hospitalizations would have required a larger sample due to their infrequency. Intention to treat analysis was used.

Results

The study is concluded, and 150 participants completed the full 12 months' study, for a 74% completion rate. Attrition was similar by group (n=74 intervention and 76 control); power was considered adequate for evaluation of primary outcomes. Groups were compared at baseline for equivalence and no significant differences were found. The sample ranged in age from 19-96 years, 51% males, with wide racial and medical diagnosis diversity. Urethral catheters were used by 56%, suprapubic 44% for mean of 6 yrs. (SD 7 yrs.). The Katz score of 7.8 for activities of daily living reflects a highly disabled population, and only 5% were employed.

The longitudinal GEE analyses for repeated measures indicated that there were no significant group differences in the 12 months of the study in the primary catheter related outcomes of CAUTI or blockage; however, there was a significant decrease (P= 0.0168) in blockage frequency in the intervention group during the first six months of the study but not for CAUTI (Table 1). The comparisons of between and within group rates at intake, for the first 6 months, second 6 months, and full study of 12 months provides additional information and indicate that both groups improved over time (Table 2).

There were far more hospitalizations in the intervention group related to CAUTI (39 in 21 persons vs. 10 in 10 persons), and these were significant differences over time (percentage hospitalized P=0.0022, frequency/counts P=0.0035, and number of days hospitalized P=0.0019). The self-rated CAUTI severity score indicated that the intervention group rated their CAUTIs as more severe than the comparison group, with a P value of 0.0392 per GEE analysis. Symptom severity was rated significantly higher *only* in the intervention group for symptoms of bladder pain, malaise, weakness, fever, and chills. Catheter related quality of life did not differ significantly for group comparisons at baseline, 6, or 12 months' follow up.

Table 1. GEE analysis of Primary Outcomes (main effects models) with baseline covariates.

Control group was reference group.

Primary Outcomes	Estimates Beta	95% Confidence Interval		P values
Main effects testing for follow up 2-6 months				
Blockage Y/N	-0.74*	-1.42	-0.07	<0.05
Blockage count	-0.52	-1.18	0.14	NS
CAUTI Y/N	-0.17	-0.69	0.35	NS
CAUTI count	-0.24	-0.63	0.16	NS
Main effects testing for follow up 2-12 months (No significant differences)				
Blockage Y/N	-0.35	-0.92	0.22	NS
Blockage count	-0.27	-1.02	0.47	NS
CAUTI Y/N	0.18	-0.26	0.63	NS
CAUTI count	0.17	-0.21	0.54	NS

Table 2. Key rates health status outcomes- between groups and within groups/1000 catheter days at Intake, First 6 months, Second 6 months & Full 12 months

	Intervention group	Control group	Between Group P values	Change from intake rates: Intervention	Change from intake rates: Control
<i>Blockage Rates</i>	Simple Rates (95% CI)			Change in rates P values	
Intake-prior two months	9.26 (6.98, 12.05)	11.5 (8.95, 14.55)	0.23		
First 6 months	4.28 (3.32, 5.43)	7.41 (6.14, 8.86)	<0.01	<.0001	0.004
Second 6 months	5.31 (4.15, 6.67)	4.45 (3.41, 5.71)	0.31	<.0001	<.0001
Full 12 months	4.76 (4.00, 5.62)	6.04 (5.20, 6.99)	0.03	<.0001	<.0001
<i>CAUTI Rates</i>	Simple Rates (95% CI)			Change in rates P values	
Intake- prior two months	6.93 (5.00, 9.37)	5.50 (3.79, 7.72)	0.32		
First 6 months	4.37 (3.40, 5.53)	4.83 (3.82, 6.03)	0.55	0.018	0.533
Second 6 months	5.48 (4.31, 6.87)	3.29 (2.41, 4.39)	0.01	0.224	0.024
Full 12 months	4.89 (4.12, 5.75)	4.12 (3.42, 4.91)	0.16	0.047	0.139

Interpretation of results

A simple-to-use catheter problems' calendar and the bimonthly interviews might have functioned like a modest form of a self-monitoring intervention for controls and affected intervention efficacy. Both groups appeared to have improved during the study. However, the intervention group might have had more serious CAUTIs which contributed to excess hospitalizations. Blockage improvement might have been related to the fluid intake component of the intervention, which lasted only the first six months.

Concluding message

Long-term catheter users might benefit from additional support/teaching beyond the timeframe of the intervention as most of the intervention was delivered in the first month, through 2 home visits, followed by a booster home visit at 4 months. Also, teaching self-monitoring skills through use of a simple calendar could help minimize catheter problems.

References

1. Khan, A., Housami, F., Melotti, R., Timoney, A., & Stickler, D. (2010). Strategy to control catheter encrustation with citrated drinks: A randomized crossover study. *The Journal of Urology*, 183(4), 1390-1394.

Disclosures

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