

## EXTENDING THE LIFE OF LONG TERM INDWELLING CATHETERS: AN RCT OF CATHETER FLUSH WITH SALINE OR ACIDIC SOLUTION VS STANDARD CARE

Complications associated with long term indwelling catheters are costly to the institution and unpleasant for the patient. These include bypassing (leakage around the catheter), urethral and bladder neck trauma, and urinary calculi, and an increased risk of bladder cancer. The most frequent and problematic are bacteriuria and catheter encrustation with subsequent blockage from struvite (magnesium ammonium phosphate) and calcium phosphate crystals. In vitro studies of catheter irrigation with 50 ml of a commercially developed acidic solution (Contisol®) shows promise in reducing encrustation. The prevalence of encrustation, blockage or bypassing of urine in catheterized patients is at least 40% and the potential quality of life and economic impact is high if an effective strategy can be found to manage long term indwelling catheters. Currently no randomised controlled trials (RCT) have been conducted in the clinical setting to evaluate the effectiveness of catheter flushes.

### Hypothesis / aims of study

In this study, we assess whether a widely used "catheter maintenance solution" is beneficial in maintaining catheter patency and thereby increasing catheter life.

### Study design, materials and methods

This is a two-centre randomized controlled trial evaluating the effect of catheter flush with Contisol, normal saline, or catheter changes as required (standard care in our setting). Sample Size: There is no published data on which to base power calculation. Based on standard practice of monthly catheter changes, we calculated that with power at 0.80,  $\alpha=0.05$ , sample size to detect a medium effect (that is three weeks longer catheter life than with no intervention) would be 30 per group.

Population/sample: Community dwelling or longterm care, English speaking individuals with MMSE greater or equal to 23 who have an indwelling catheter in situ longer than 30 days and who require catheter changes because of blockage more than once a month. Subjects and their families are given an information leaflet by the unit or homecare manager. Interested subjects contact the unit manager or homecare nurse to discuss participation. After informed consent is signed, baseline data is collected using standardized tools to record medical and urologic history, reasons for indwelling catheter, catheter history, fluid intake and bowel care. On the next planned catheter change, subjects are randomized to one of the three arms.

Primary outcomes: time to first change and number of changes over the 8 week period; secondary outcomes: staff and subject satisfaction with the protocol, cost, incidence of symptomatic UTI, haematuria, pyuria, and urine pH.

### Results

To date, 99 subjects have been screened and 69 randomized (25 Contisol; 19 Saline; 25 No intervention). Preliminary results suggest a drop in the number of catheter changes per month from 2.5 to 1.0 ( $p<.001$ ) in the irrigation groups compared to the standard care group. No adverse events have occurred. On weekly urine dip (Chemstrip), nearly all subjects had positive leukocytes and microscopic haematuria 100% of the time. One subject developed a symptomatic UTI (fever, chills). Two unexpected findings are noteworthy: 1) many subjects in the study have been prescribed antibiotics for non-symptomatic bacteriuria, odour in urine, or cloudy urine; and 2) knowledge about proper catheter support to prevent urethral trauma, knowledge of evidence on routine changing, and knowledge of method for obtaining urine for culture and sensitivity from a catheterised patient is fair, suggesting that improved education concerning standards of practice for long term indwelling catheter care may be needed for both nurses and physicians. A complete analysis based on a sample of 20 per group will be further described in the presentation.

### Interpretation of results

Practice guidelines for catheterised patients are not routinely adhered to and supportive healthcare professional education may be required combined with as well as exploring the rationale for non-adherence. Catheter care is a major issue for caregivers, the patient, and for homecare staff and hidden costs such as laundry, carpet or floor cleaning, and trips to the physician are significant. We are unable to state, at this point, whether catheter flushes increase time to first change.

### Concluding message

Catheter blockage places a major burden on patient quality of life and family dynamics. If routine catheter flushes can prolong catheter life for individuals with longterm indwelling catheters and reduce the number of changes required, significant savings in patient comfort, homecare nursing time, and healthcare dollars may be realised.

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**CLINICAL TRIAL REGISTRATION:** This clinical trial has not yet been registered in a public clinical trials registry.

**HUMAN SUBJECTS:** This study was approved by the Health Research Ethics Board (HREB) University of Alberta; HREB Calgary Health Region Alberta Canada and followed the Declaration of Helsinki Informed consent was obtained from the patients.

