Avoiding Urinary Tract Infections in Patients practising Intermittent Catheterization

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Introduction/ summary:

Poor bladder emptying is a well-known phenomenon in urology. Urine remaining in the bladder increases the risk of urinary tract infection.
Effective bladder emptying therefore is essential. This may be performed by draining the bladder intermittently by means of a disposable catheter or by an indwelling catheter. The method emptying the bladder intermittently is called clean intermittent (self) catheterisation (CIC). Nowadays CIC is a commonly recommended procedure for people with incomplete bladder emptying in order to protect the bladder and renal health. It involves several times a day the insertion of a disposable catheter into the bladder, outflow of the urine and removal of the catheter. (Achterberg et al., 2006)

Urine normally does not contain microorganisms, but if urine is retained in the bladder, it provides a good environment for bacteria to grow.
The most frequent complication of CIC is bacteriuria. In general asymptomatic bacteriuria will not be treated. However bacteriuria can cause urinary tract infections and give complications as pyelonefritis, epididymitis and prostatitis.
Bacteria growing around the meatus can be introduced into the urethra to manifest an UTI. Catheterisation can cause such introduction. The microorganisms stick to the wall of the urethra, multiplying and moving up the urethra to the bladder. Most UTI remain in the lower urinary tract, where they cause symptoms such as urgency and burning sensation during micturition.
The blanket term UTI is frequently used, but a urinary tract infection may also be identified by the part of the urinary tract affected. Urethritis is an inflammation and/or infection of the urethra. Bladder involvement is called cystitis, and when one or two of the kidneys are inflamed or infected, it is called pyelonephritis.
In this study UTI is defined as the combined outcome of bacteriuria (10^5 CFU/ML) and pyuria (> 10 white bloodcells)and one or more of the following symptoms; frequency, urgency, dysuria, stranguria or haematuria.

According to recent literature, approximately 30% of CIC patients get bacteriuria and 7-10% of the patients using CIC will get UTI and need to be treated with antibiotics (Rew. 2003). However, these numbers do not seem to reflect reality and underreport the number of UTI. For example in our hospital in the last two years, 32 % of the new CIC patients (n=123) got UTI within 6 months after starting CIC. This high incidence means that more and more patients are treated with antibiotics by general practitioners/urologists.

To detect a UTI urinalysis is needed. The most common way to analyse urine is by means a simple reagent strip. In this way abnormalities in the urine can be detected. A positive nitrite test on a reagent strip indicates bacterial infection. Pyuria also indicates bacterial infection. If there are no symptoms, antibiotics are normally not required. If systematic symptoms are present, full microbiological analysis is warranted to prescribe specific and sensitive antibiotics.

Suffering from an UTI influences patients quality of life. (Ellis. 2000). This may lead to absence of work, loss of quality of life, taking more medicine etc., resulting in more costs.

In this project we will investigate both a technical intervention (catheterization) and an educational intervention to prevent UTI and recurrent UTI. We aim to spend the award on the educational intervention, whereas financial support is applied for by other parties for the catheterization arm.

Objectives:

1   To determine the incidence of UTI in patients in our hospital and intended other hospitals using CIC to empty their bladder.

2   To determine if any catheter type (hydrophilic coated catheter, hydrophilic coated catheter using insertion-aid, hydrophilic coated catheter using full protective sleeve) can reduce the number of UTI.

3   To determine if additional long-time coaching of CIC patients can reduce the amount of UTI.

Hypothesis:

- Hydrophilic coated catheter using full protective sleeve will reduce the number of UTI (Figure 1, group A1 and A2 versus group C)
- Additional long-time coaching of CIC patients will reduce the number of UTI (Figure 1, group B versus group C)
- Reduction of UTI is related to improved quality of life, less visits to a general practitioner and less healthcare costs

Literature review:

Clean intermittent catheterization(CIC) is the preferred method of catheterization in patients who have bladder dysfunction (Lapides et al., 1972). By means of intermittent catheterisation patients with poor bladder function can prevent prolonged accumulation of urine and urinary tract infections (UTI). Although CIC insures bladder management to prevent complications as UTI and hydronefrosis, long-term catheterization can also cause UTI (de Ridder, 2005). For example poor maintaining of not following instructions or poor hygiene can lead to bacteriuria and inflammation and subsequently pyelonefritis (Getliffe, 2006).
Hence prevention of UTI is decisive and should be part of medical and nursing care.

To a large extent the care for CIC patients is not evidence-based. Some studies state that hydrophilic catheters might reduce UTI (Jaquet, 2009). However clinical nursing experience suggests an increase of UTI in CIC patients.

In our country outpatients with signs of UTI normally will see a general practitioner. To diagnose a possible UTI, an urinalysis by means of a simple reagent strip is the standard procedure. If there is an infection, treatment with a broad-spectrum antibiotic will be started according to Dutch GP guidelines (NHG standard).
This can result in antimicrobial resistance and expending of costs.

In summary, UTI are commonly seen in CIC patients. This can have great impact on patients and healthcare expenders. However treatment and prevention of UTI in CIC patients are largely not evidence-based. Prolonged education of patients, using the right materials for CIC might reduce the number of UTI in CIC patients.

Relevance to urology nursing:

The (nursing) care for CIC patients is largely not evidence-based. Further research is needed to find out which treatment and which materials are best. Especially, since this might prevent UTI and in that way improve health-related quality of life and reduce healthcare costs.
If additional education of CIC patients by nurses or any type of material can lead to a reduction of UTI, this should become part of the high-quality care we as (urology) nurses intend to deliver.
Next step will be that these ways of acting become part of the standard care training of (urology) nurses.

Methodology:

Study design and participants:

The study will be a prospective (optional: multi-centre) randomized controlled trial. Patients starting with CIC will be asked to participate in this study and will be randomised into one of three groups, i.e.

(A) Catheter intervention group; (B) Educational intervention group; (C) Control group. To sufficiently power the study a total number of 380 patients will be needed. We do not expect a high-drop out since the interventions are not invasive nor intensive and they are embedded in regular care.

The following patients will be excluded for the study:

- Patients younger than 18 years
- Patients who are pregnant
- Patients having an urinary tract infection at baseline or less than three month ago
- Patients mimicking urinary tract infections (yeast vaginitis, interstitial cystitis)
- Mentally-retarded patients

For this study approval will be requested by the Medical Ethics Committee (MEC)

Power calculation

The final endpoint in this study is the occurrence of UTI. In patients starting CIC in the last two years, the prevalence of UTI within six months after starting CIC was 32%. A reduction to 16 % is considered relevant. The intended numbers of 95 patients in each group allow detecting halving the occurrence of UTI in the intervention groups compared to the control group C with a power of 80% ($\alpha = 0.05$). In other words with these numbers a clinical relevant difference between 32% and 16% will be statistically significant as well. (The lower bound of the 95% Confidence Interval for 30% UTI is 22.3%, and the upper bound for 16% UTI is 22.2%) In the other outcomes of the study (e.g. bacteriuria, health-related quality of life), lower numbers already provide sufficient statistical power, since these outcomes are measured at an interval level.

Randomisation Procedure

Patients will be stratified on age (>65 yrs or ≤65 years), on gender and on voiding. Patients either are totally non-voiding or will have a residue of more than 100 ml after voiding. Then patients will be randomised into three groups (see also Figure 1)

Group A: Catheterization Intervention Group. This group will be further randomised in a group (A1, N = 95) that receives a catheter without an insertion aid and a group A2, N = 95) that receives a catheter with a full protective sleeve. The numbers in the

subgroups allow detecting a 50% (16% vs 32%) difference in the occurrence of UTI compared to the control group C with a power of 80% (α = 0.05)

A1: Hydrophilic coated catheter without insertion aid.
To introduce the catheter into the urethra it needs to be touched by hand.

Fig 1:Example of a hydrophilic coated catheter without aid

A2: Hydrophilic coated catheter with a full protective sleeve.
To introduce the catheter into the urethra the catheter it self can not be touched by hand.

Fig 2: Example of a hydrophilic coated catheter with full protective sleeve

<u>Hypothesis for group A:</u> Hydrophilic coated catheter using full protective sleeve will reduce the number of UTI.

Group B: Educational Group (N = 95), who will receive additional coaching by a trained nurse specialist. The additional coaching will be focussed on techniques of using the catheter, how to use it in the home setting (also work, leisure time) and preventing UTI. Also reinstruction of the standard education (see Group C)
The numbers in the subgroup allow detecting a 50% (16% vs 32%) difference in the occurrence of UTI compared to the control group C with a power of 80% (α = 0.05)

<u>Hypothesis for group B:</u> Additional long-time coaching of CIC patients will reduce the number of UTI

Group C (N = 95): Control group, receiving standard care according to treatment in our hospital. That is a catheter with insertion aid and standard education according to the guideline VenVN CVV (Verpleegkundigen en Verzorgenden Nederland afdeling Continentie Verpleegkundigen en Verzorgenden); association of Dutch nurses and carers department of continence-care.
Standard education is a visit of one hour to receive information about CIC and catheters, practising CIC and evaluation after one week, three months and one year.

In this group a hydrophilic catheter with insertion aid will be used that enables inserting the catheter into the urethra without touching.
To introduce the catheter into the urethra an insertion aid can be used.
Nevertheless contamination remains possible if the insertion aid is not used correctly.

Fig 3: Example of a hydrophilic catheter with insertion aid.

<u>Measurements:</u>

The primary outcome is the incidence of new or recurrent UTI in CIC patients.
UTI is defined as the combined outcome of bacteriuria (10^5 CFU/ML) and
pyuria (> 10 white bloodcells) and one or more of the following symptoms; frequency, urgency, dysuria, stranguria or haematuria.
Urinary analysis will be based on a reagent test and if positive (for nitrite) as well on full-microbiological analysis.

The Secondary outcomes are:
- The impact of UTI in daily life measured by questionnaire and interviews
- Self-care behaviour, measured by interviews
- Health related quality of life measured by the Rand-36 (Van der Zee 1993)
- Health-care consumption based on hospital records/patient files and a checklist for patients

Confounders are patient characteristics (e.g. gender, age, educational level) and clinical features (e.g. disease status).

All measurements (except demographics) will be done at baseline, one month, three months and twelve months follow. In case of an UTI, the patient's status with respect to UTI will be followed till one year after the diagnosis.

Feasibility:

In our hospital approximately 75-100 patients are instructed to use CIC per year. In this study we need 380 patients. Therefore this study will be divided in several parts according to the following plan:

First year:
- Determination the incidence of UTI in CIC patients
- Preparation of the interventions

Second and third year:
- Randomization and follow-up for the use of different types of catheters
- Randomization and follow-up for standard education / additional education

First to Fourth year:
- Writing manuscripts

Articles to be written
Chapters :
I   Review intermittent catheterization (first year)
II   Incidence of UTI versus literature (first and second year)
III   Results catheter group (second to fourth year)
IV   Results additional education group (second to fourth year)

To give more expressive power to this study and make it more comparable we intend to enlarge it to multi centre. A multi centre setting will also reduce the total duration of the study.
We already found one hospital interested to participate. We intend to find one or two more participating hospitals.

Budget:

A) Research Nurse
   Salary costs, including social taxes (4 years, 25%)   **€   70.000**

B) Secretarial assistance / data-management support (380 hours)   €   8.600
    Statistical and methodological assistance (40 hours)   €   2.400
    Total   **€   11.000**

C) Other costs
    Setting, posting and copying of questionnaire, reminders (380*4) €   7.600
    Catheterization materials (= regular care)   €   0
    Dipstick and lab tests for UTI (additional to regular care)   €   10.000
    Preparing educational intervention, writing SOPs and training of educators €   2.000
    Conference visit (to present results)   €   2.500
    Total   **€   22.100**

D) Patient reimbursement
    Travel expenses for two additional visits   €   7.600

Budget: € 110.700
Overhaed (10%):   € 11.070
Total: € 121.770

Conclusion:

CIC is a common procedure in patients with incomplete bladder emptying in order to protect the bladder, renal health and prevent prolonged accumulation of urine and urinary tract infections (UTI). Although CIC insures bladder management to prevent complications as UTI and hydronefrosis, long-term catheterization can also cause UTI. To a large extent the care for CIC patients is not evidence-based. Therefore more studies are needed.
Reduction of UTI may be seen if a patient is coached in CIC during a longer period. If a totally sleeved catheter reduces the chance of UTI, it should become part of standard (urology) nursing care.
A reduction of UTI can have a positive impact on patients and healthcare expenders.
Less UTI in CIC patients will lead to a reduction of taking medicine (antibiotics) and less costs in healthcare.

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Conflicts of interest:

Henk-Jan Mulder is member of the:

Advisory board Hollister in the Netherlands
Advisory board Braun in the Netherlands