

Which factors make Clean Intermittent (Self) Catheterisation successful?

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1. Introduction

Clean Intermittent (Self) Catheterisation (CI(S)C) was introduced by Lapedes et al. in 1972 (12). They advocated the use of CI(S)C to improve the lives of patients with micturition disorders. The use of intermittent catheterisation of the bladder reduces the incidence of over-distension and it is now an accepted form of treatment for neuropathic bladder dysfunction as well as many other causes of bladder-emptying problems ((2, 22). CI(S)C replaces long-term indwelling catheters from which is proven that they cause urinary tract infections (2, 11, 15, 22). This and other catheter problems such as blockage, encrustation, catheter rejection, pain and trauma, non compliant bladders and squamous cell carcinoma are greatly reduced by the use of CI(S)C (2, 11,15, 22). Nowadays, the technique of CI(S)C is applied to all age groups including newborn as well as the elderly, and has become an important therapeutic tool in urology. Right from the start nurses were involved in this treatment and nowadays, in most countries, nurses teach and coach CI(S)C to patients (20).

At the last congress of the EAUN (Vienna 2010), there was a symposium about 'The Psychosocial Impact of Intermittent Catheterisation'. After this lecture we discussed that we need good studies to investigate which factors influence learning and adherence of CI(S)C. The current literature consists of mostly retrospective studies or case-studies with a small sample size. In these studies, the method of teaching the procedure, coaching and follow-up mostly was not clear, so it is difficult to compare these studies. Besides this, only a few studies describe the reasons why patients have to stop with CI(S)C. None of them include reasons why patients decided not to start with CI(S)C or why the initial training was not successful.

Between 2004 and 2006 a study has been done in the Netherlands to evaluate which factors influence the adherence of CI(S)C (19). This study of 30 patients gave a first insight in relevant factors in CI(S)C adherence as a starting point for care innovation and future research. Referring to this investigation a care innovation took place. This innovation included the implementation of a national protocol for continence nurses and the development of a non-commercial information brochure for patients. The protocol contains a detailed description of the procedure and of the follow up care. The society of continence nurses of the Netherlands (CV&V) became the owner of these products and the protocol. The protocol was adapted in the national educational program for continence nurses, where it is a part of the training course about CI(S)C. The production of the brochure is supported by several medical companies and medical services. These innovations were implemented between 2006-2007 (6). At this moment most of the health care institutions teach and coach patients who need to perform CI(S)C according to this protocol.

Summarized, we can conclude that CI(S)C has become an important therapeutic tool in urology. Right from the start nurses were involved in this treatment and nowadays, in most countries, nurses teach and coach CI(S)C to patients. By investigating the factors that influence the teaching procedure and adherence of CI(S)C, we can bring urology nursing to a higher level and improve Quality of Life (QoL) for patients who need to perform CI(S)C.

2. Objectives

Overall goal

The objective of this study is to investigate which factors influence the teaching procedure and adherence of short- and long-term CI(S)C.

Specific objectives

- What are the specific causes for failure of CI(S)C?
Our hypothesis is that physical causes like disturbed hand function, severe disability, visual impairment and especially in women severe obesity can influence this objective as well for the patient him/herself as for a caregiver. But also medical causes like Urinary Tract Infection (UTI) and a prolapse in women as well as psychological factors like motivation, higher frequency of CI(S)C per day, cognition, benefits of CI(S)C to the patient also can influence this objective.
- Does CI(S)C change Quality of Life (QoL) ?
Our hypothesis is that if the patient has benefit of CI(S)C, it will change QoL in a positive way.
- Does age influence the teaching procedure and adherence of CI(S)C?
Our hypothesis is that age is a risk factor, because of co-morbidity like cognitive, physical and psychological status, but also mucosa atrophy or BPH in men. However, when these factors have been explored and discussed with the patients, they can learn the technique of intermittent self-catheterisation. Not offering the possibility of CI(S)C to the elderly is unjustified and withholds them from the possibility of improving their QoL (16).

3. Short literature review

According to the ICS standardisation sub-committee (1), Intermittent Self-Catheterisation (ISC) is performed by the patient him/herself. Intermittent Catheterisation (IC) is performed by an attendant. For Clean Intermittent Catheterisation (CIC) a hygienic technique is used, which implies ordinary washing techniques and use of disposable or cleansed reusable catheters. In the literature different terms are used in a confusing way, e.g. CIC, SCIC, clean-ISC.

In this project, we will use the term Clean Intermittent Self Catheterisation (CISC) when the person performs intermittent catheterisation him/herself, and CIC when intermittent catheterisation is performed by an attendant. When using CI(S)C both groups are meant. The CI(S)C procedure is often considered to be both simple and safe and is associated with improved quality of life in patients (7,10), because increased social freedom and independence can result from successful performance of self catheterisation (8, 9, 20). However, some studies also report negative quality of life issues such as embarrassment, lack of confidence and strain on family relationships (14, 5). Furthermore, the 'simplicity' of CI(S)C seems assumed, rather than factual. Patient adherence with CI(S)C is hardly addressed in clinical studies and factors facilitating or hindering adherence are largely unknown. WHO (21) describes how non-adherence is a major problem in all long-term therapies. Non-adherence to CI(S)C procedures and frequency can cause complications of the urinary and renal tract and deserve to be monitored by health professionals. In a literature review, Rew and Woodward, 2001 (21) concluded that determinants of CI(S)C adherence should be studied, to facilitate improved professional support in patients. However, studies describing relevant factors in CI(S)C adherence are lacking. In current practice, the quality of patient education and the amount of follow-up support given varies widely (3). It is not clear to what extent adherence is addressed in CI(S)C-instruction

sessions or follow-up care. The need for good quality instructions and follow-up care however, is generally acknowledged (8, 22).

The aim of the study of Van Achterberg, 2008 (19) was to explore factors that hinder or promote adherence to CI(S)C procedures in adults. A group of 30 patients was investigated of whom 13 were 65 years or older and they were investigated as a separate group. Most adherence problems at short-term were related to: knowledge, complexity of the procedure, misconceptions, fears, shame, motivation and timing of the instruction session. These determinations illustrate how CI(S)C is not as simple as is often assumed. Obtaining the knowledge required and mastering necessary skills, can be a real challenge to patients. In addition, issues of fears, motivation and shame underline that adherence to CI(S)C goes beyond knowledge and skills. These findings illustrate how some patients struggle with psychological adjustment to the need to perform the procedure. Long-term adherence problems are: fears of negative effects, who may persist over time, lack of follow-up care by professionals and self-efficacy in patients. Patients perceive the combination of CI(S)C and having an active social life as difficult and seem to choose from either avoiding activities or non adherence to prescribed CI(S)C frequency. Some problems are specific for elderly: women mastery is complicated by limited knowledge of their bodies, and older patients tend to avoid situations that compromise adherence. The conclusion of Van Achterberg, 2008 (19) was that this study gave a first insight into relevant factors in CI(S)C adherence as a starting point for care innovation and future research.

In the literature we only found a few articles specific about CI(S)C and ageing people. These articles show that CI(S)C is possible for the elderly (3), but sometimes more follow-up care is needed. There are lots of barriers, but most of them seem common for all people. Pilloni, 2005 (16) stated that older people with adequate cognitive function, mobility, motivation and manual dexterity, easily learn the technique of CI(S)C, and not offering CI(S)C because of older age is unjustified and withholds older people from the possibility of improving their quality of life'. Shaw, 2007(18) stated that patient centred care is important for teaching and supporting CI(S)C as well as during follow-up care. Logan, 2007 (13) states that healthcare professionals' communication skills and attitudes are instruments for promoting confidence in carrying out the procedure and results in better long-term compliance. But, more investigations are needed about CI(S)C and elderly people. In these articles the age was a discussion point. 60, 65, and 70 years and older were inclusion criteria. Besides that, not all articles described how the teaching program & follow up care was done and organized, which makes it difficult to compare these articles.

4. Relevance to urology nursing

With this study we want to obtain further insight in which factors make CI(S)C successful, to provide urology nurses with sufficient guidance to develop the quality of their instruction, coaching and follow-up care for patients that need to perform CI(S)C. Identifying risk factors may help to customize treatment approaches and make CI(S)C a more successful treatment.

5. Methodology

Type of design

Our study design:

- Will be a multicenter study (including a university hospital, a general hospital and a rehabilitation center) so we can include a variety of diagnoses for CI(S)C.
- Will be a prospective study.
- Will contain short and long-term results, with a follow-up at 1 week, 3 months and 12 months.

Study procedures

- 150 patients will be included.
- The patients will be instructed according to the national guideline, by 6 continence nurses/nurse specialists in 3 centers.
- Data obtained will be:
 - Patient specific questionnaire (see attachment A)
 - Patient specific characteristics
 - If applicable, a Likert scale is used
 - VAS-scale for QoL on voiding problems (see attachment B)
 - CI(S)C in daily practice questionnaire (see attachment C)
 - Bladder management questionnaire (see attachment D)
 - If patient refuses to start CI(S)C, or if the urologist thinks that a patient is definitely unable to start CI(S)C: reason for refusing, or for not starting. The medical specialist will inform the continence nurse why refusing/not starting.
 - If patient doesn't succeed to learn CI(S)C: reason why
 - If patient quits the treatment in short- or long-term: reason why
 - When patient doesn't start CI(S)C, or if he doesn't succeed or quits treatment: record alternative treatment.

Study population

- Inclusion criteria:
 - Patients who are referred for CI(S)C
 - Patients 18 years and older, who understand the Dutch language and are able to fill in the questionnaires.
 - CI(S)C must be necessary at least once a day
 - At start of the treatment: CI(S)C is advised to be performed for at least 3 months
- Exclusion criteria
 - CI(S)C used for dilatation of the urethra

Outcome measures

- How many patients didn't start, didn't succeed or quitted treatment?
- Find reasons why patients refuse, don't succeed, or quit CI(S)C.
- Does CI(S)C change QoL?
- How is the QoL of the CI(S)C performing group compared to the group that quitted or didn't start CI(S)C?
- Find complementary outcomes on teaching and adherence of CI(S)C.

Statistical analysis

Data will be evaluated using computer software Statistical Package for the Social Sciences (SPSS). A significance level of $p < 0.05$ is chosen and data are reported as mean \pm standard error.

Sample size

A sample size of 150 patients will be included.

6. Feasibility

Timetable

Develop project plan	June-October 2011
Develop questionnaires	June-October 2011
Evaluation of the questionnaires	November-December 2011
Project plan to ethic committee	October-December 2011
Inclusion of patients	March 2012-2013
Statistics & evaluation short-term	April-June 2013
Statistics & evaluation long-term	June-December 2013 and further
Presentation EAUN	March 2014

Budget EAUN

Administration	€ 500
Statistical costs, presentation, writing article	€ 2000

For calculation of long-term results we will look into possibilities of obtaining a company grant.

7. Conclusions/Relevance

CI(S)C has become an important treatment in urology. Right from the start nurses have been involved in this treatment and nowadays in most countries, teaching and coaching CI(S)C to patients is performed by nurses (20). It is important that we obtain more evidence based insights in which factors are crucial for failure or success of CI(S)C.

In this large sized, prospective multicentre study, we will try to find answers to these questions.

8. State any possible conflicts of interest

None

9. References

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Attachment A: Patient specific questionnaire

Baseline

Hospital

- University hospital
- General hospital
- Rehabilitation center

Referring specialist

- Urologist
- Gynecologist
- Rehabilitation physician
- Otherwise:.....

Age

Year of birth.....

Gender

- Male
- Female

Physical characteristics that could affect CI(S)C, in the view of the investigator.

- Obesity
- Prolapse
- Severe spasms
- BPH
- Mucosa atrophy / Lichen Sclerosus
- Visually impaired
- Otherwise:

Education level

- Primary
- National certificate
- National diploma
- Advanced level
- University / science education

Diagnosis

- Neurogenic
 - Multiple Sclerosis
 - Tethered Cord Injury (= also CES, CMS)
 - Spina bifida
 - Otherwise:.....
- Non neurogenic
 - Post void residual urine
 - Urinary retention as a result of surgery (for example TVT, BTA)
 - Recurrent UTI without apparent cause

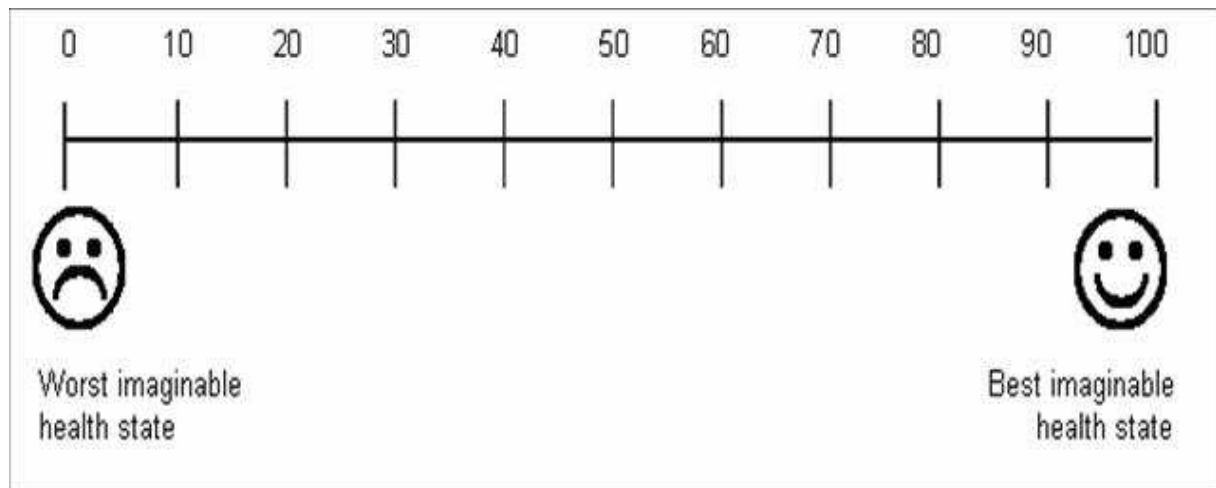
- Otherwise:.....

Reason CI(S)C

- Post void residual urine
- Urinary retention
- Urgency / frequency
- Otherwise:

Attachment B: VAS-scale QOL in voiding problems

- Baseline
- 1 week after start CI(S)C
- 3 months after start CI(S)C
- 1 year after start CI(S)C



Attachment C: CI(S)C in daily practice questionnaire

- Baseline**
- 1 week after start CI(S)C**
- 3 months after start CI(S)C**
- 1 year after start CI(S)C**

Hand function

- Steady hand function
- Impaired sensory function in normal hand
- Reduction of fine hand motor one hand
- Reduction of fine hand motor both hands
- No hand function

Cognition

- Patient is able to repeat the information provided
 - Yes
 - No
 - Doubtful
- Patient is able to execute the instruction
 - Yes
 - No
 - Doubtful

Mobility

- Walking is undisturbed
- Walking difficult, but possible without aids
- Walking with aids
- Wheelchair-bound, but standing transfer
- Fully wheelchair-bound

Specific medication

- Antibiotics
 - Maintenance dose
 - Antibiotic during current measurement
 - Some antibiotics since last measurement
- Anticholinergics
- Both not applicable

CIC/CISC

- CISC independent
- CISC with tools
- CIC by partner or relative
- CIC by a professional

Catheter

- Brand.....
- Name.....
- Charrière

Use of catheter

- Inapplicable because of baseline measurement
- Same as at start CIC
 - Yes
 - No, reason.....

Frequency of catheterisation per day

- 1 x
- 2 x
- 3 x
- 4 x
- 5 x
- 6 x
- Otherwise:x

Frequency of CIC/CISC

- Unchanged
- Increased: now..... x
- Decreased:now..... x

Attachment D: Bladder management questionnaire

- Baseline**
- 1 week after start CI(S)C**
- 3 months after start CI(S)C**
- 1 year after start CI(S)C**

Patient refuses to start CI(S)C. (Only at baseline)

- Not applicable
- Reasons
 - Physical
 - Medical
 - Psychological

Medical specialist thinks that a patient is unable to start CI(S)C (Only at baseline)

- Not applicable
- Reasons
 - Physical
 - Medical
 - Psychological

Continence nurse thinks that a patient is unable to start CI(S)C (Only at baseline)

- Not applicable
- Reasons
 - Physical
 - Medical
 - Psychological

Time patient stopped

- CI(S)C not continued after instruction
- Stopped < 1 week after start
- Stopped > 1 week < 3 months after start
- Stopped > 3 months < 1 year after start

Reason of quitting

- Not applicable
- Patient or relative cannot perform CI(S)C / CIC
 - Physical
 - Medical
 - Psychological
- Patient does not see the profit
- No improvement noticed
- Restoration of normal bladder function / voiding
- Deceased
- Otherwise:.....

Patient doesn't succeed to learn CI(S)C

- Not applicable
- Reasons
 - Physical
 - Medical
 - Psychological

Patient quits the treatment

- Not applicable
- Reasons
 - Physical
 - Medical
 - Psychological

If not proceeding with CI(S)C, what is the alternative treatment?

- Not applicable
- None
- Indwelling catheter (Supra Pubic Catheter /Transurethral Catheter)
- Use of incontinence materials
- Urostomy
- Otherwise:.....