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Short Term Evaluation of a Novel Eletronic Transanal Irrigation System in Patients with Neurogenic Bowel Dysfunction Previously Exposed to Transanal Irrigation Systems

Short Title: Navina Smart for Neurogenic Bowel Dysfunction

Passananti V.[1], Emmanuel A.[1], Nordin M.[2], Storie J.[1], Gripenland J.[2], Astrom M.[3] and Hultling C.[2]

1. GI Physiology Unit, University College London Hospital and National Hospital for Neurology & Neurosurgery, London NW1 2BU, UK

2. Karolinska University Hospital, Department of Neurology, Stockholm141 86, Sweden

3. Biostatistical department, StatCons, Malmö 126 18, Sweden

Abstract: Introduction: Neurogenic bowel dysfunction is one of the most distressing consequences of the spinal cord injury. Transanal irrigation has proven to be a treatment for many such individuals, but there are some patients with sub-optimal response to it. Our aim was to evaluate the satisfaction, safety, perception and compliance of a new transanal irrigation device, Navina Smart system featuring an electronically driven pump with a digital control. Material and methods: Twenty-eight patients who had previously used, or were currently using transanal irrigation were enrolled. They were trained to use the Navina Smart system and were thereafter treated for four weeks. Patient perception, compliance and level of satisfaction were assessed at baseline and at the end of treatment. Results: At the end of treatment 68% of patients were still using the system and 50% of ITT (intended to treat) wished to continue using the system. Navina Smart was well tolerated with no adverse effects in the cohort. Patient perception of the Navina Smart system was positive in 67%. Conclusions: Navina Smart system was shown to be safe, tolerable and effective in two-thirds of patients who were unsatisfied with their previous bowel care and was associated with an increase in the patient's independence.

Key words: Navina™ Smart system, neurogenic bowel dysfuction, transanal irrigation.

1. Introduction

NBD (neurological bowel dysfunction) is a common problem in patients with diseases affecting the central nervous system, such as SCI (spinal cord injury), MS (multiple sclerosis) and SB (spina bifida) [1-3]. These patients experience constipation, faecal incontinence or a combination of these two symptoms. Indeed more than 65% of SCI and MS patients report bowel symptoms [4]. First line therapy for NBD involves alteration of lifestyle and diet, and beyond that use of oral laxatives combined with suppositories and digital manoeuvres to assist voiding. However, conservative bowel management is often not effective and can be difficult to adopt [5]. Such standard bowel care often requires a lot of time and may compromise the independence of patients. The symptoms of NBD not only have a great impact on self-esteem [1, 6-8] (with social restriction having a major impact on work and personal relationships) but are also a source of co-morbidities such as rectal bleeding, limb spasticity

Corresponding author: Valentina Passananti, M.D., MBBS MSc medicine, clinical research fellow, Ph.D student, research fields: neurogastroenterology.

and urinary infections [9-12].

When such standard bowel care is unsatisfactory the next line of therapy is TAI (transanal irrigation) [13]. Patients and/or carers are instructed in the technique, which is intended to assist the evacuation of faeces from the bowel by introducing water via the anus. It can be done without assistance from another person, providing the access to a toilet or commode. The improved self-esteem that is associated with such independence in managing the bowel is a significant factor in the often reported finding that TAI improves quality of life, reduces time spent on bowel management and most importantly reduces episodes of faecal incontinence. The latter is otherwise the most important social restriction for NBD patients [14].

We aimed to study a new product, the Navina™ Smart system, which is suggested to enable independent trans-anal irrigation for patients. The electronic control unit permits irrigation with the push of a button without the need for hand strength and coordination to control the flow of air and water. The aims of the study were to investigate the compliance, perception and level of satisfaction in a group of patients with prior unsatisfactory attempts at TAI therapy.

2. Materials and Methods

We undertook a prospective, qualitative, single arm multicentre study using of a novel transanal irrigation system in a population with NBD who had been exposed to TAI. We enrolled patients from inpatient and outpatient neurogastroenterology and neurology clinics in two European specialist centres, University College Hospital (London) and the Karolinska University Hospital (Stockholm). Observational data were collected for a period of 4 weeks of treatment with the Navina Smart system. Information was collected using a standard questionnaire, comprising data about compliance, satisfaction and perception.

For inclusion in the study the patients had to fulfil all of the following criteria: aged 18 years and over, either sex, having used TAI for at least 2 months and at least twice per week, able to read and complete a paper outcome questionnaire and provision of informed consent. Exclusion criteria were the following: any previous radiotherapy to the pelvis, current treatment with anticoagulants, untreated rectal impaction, current long term systemic steroid medication, any rectal or colonic surgery, rectal or colonic endoscopic polypectomy within the previous four weeks, overt or planned pregnancy, symptomatic urinary tract infection at time of enrolment, psychiatric illness considered unstable by the investigator, participation in another clinical study within the last 30 days that may interfere with the present study.

2.1 Study Design

At the baseline visit the patient completed a 12-question Baseline Questionnaire (Appendix A) evaluating the patient's bowel management and the TAI system the patient was using or had used up until the baseline visit. Medical and surgical history was also collected. The study staff trained the patient in how to use Navina Smart system. At 7 and 14 days the patient had follow-up appointments by phone to determine the patient's compliance with Navina Smart and if they had experienced any issues or health problems since they started using it. After 4 weeks at the follow-up visit, the patient attended the unit and completed a 25-question follow-up questionnaire about the use and experience of using Navina Smart (Appendix B). Any changes to current medications and any experience of issues or health problems during the study were documented.

2.2 Study Device

Navina Smart has been developed by Wellspect HealthCare and consists of a hydrophilic rectal catheter with an inflatable balloon, tubing and water container and handheld electronic control unit (Fig. 1). By pressing lightly on the buttons on the handheld

Fig. 1 Navina™ Smart system (control unit, water container and rectal catheter).

control unit, the balloon on the rectal catheter can be inflated and deflated, and water volume can be instilled at a steady pre-set rate. The health care professional and patient can also pre-set the limits for balloon inflation and irrigation on the control unit and lock these in place.

2.3 Ethics

The study (title: Evaluation of a Novel Eletronic Transanal Irrigation System-Navina Smart) was granted approval by the Cambridge East Research Ethics Committee REC number 15/EE/0460. The study was conducted between 10/02/2016 and 23/09/2016.

2.4 Statistical Method

The sample size was not based on statistical power but chosen to be logistically manageable in this observational non-comparative study. Descriptive statistical method was used in the analysis of study data. As descriptive statistics we used frequencies and percentages for categorical data. Testing the hypotheses that the change over time within the group was equal to zero was done using the non-parametric Wilcoxon signed rank test. Two-sided p-values below 5% were considered statistically significant results.

In the analysis of the patients' satisfaction and perception the ITT (intention-to-treat) subset of patients was used. In the analysis of the compliance the PP (per-protocol) subset of patients was used. In the analysis of safety the ITT subset of patients was used.

3. Results

We enrolled 28 consecutive patients with the inclusion criteria (14 from each site), 17 male and 11 women with a mean.

All patients were currently using another TAI system, and 16 of them (57%) for more than three years. Twelve (43%) were irrigating daily and 21% on alternate days. All reported sub-optimal performance and hence were seeking an alternative. Nineteen of the cohort (68%) had no restriction of hand function 32% impaired function. Seventeen (61%) used a wheelchair (18% impaired walking, 21% ambulant). Spinal cord injury was the cause of NBD in 19 patients, with MS in four, SB in two and a variety of other neurological diseases in three (Fig. 3).

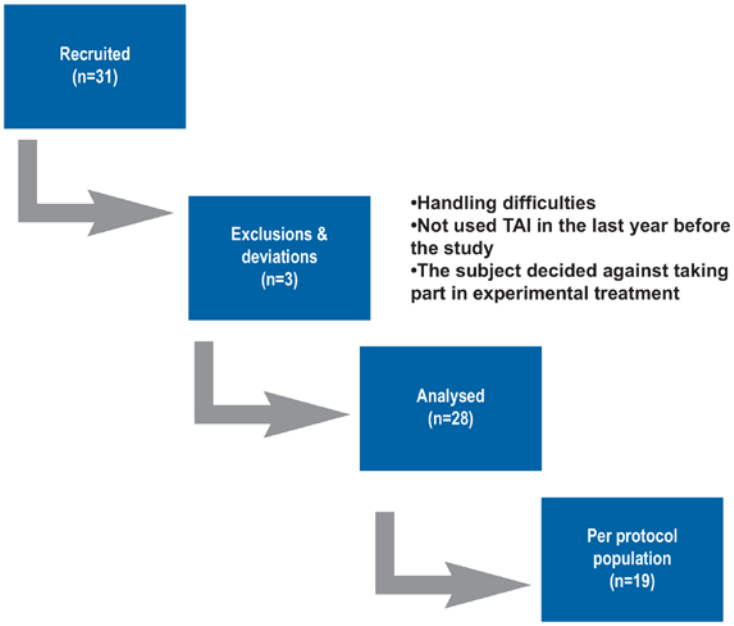

Fig. 2 Flowchart for the study analysis.

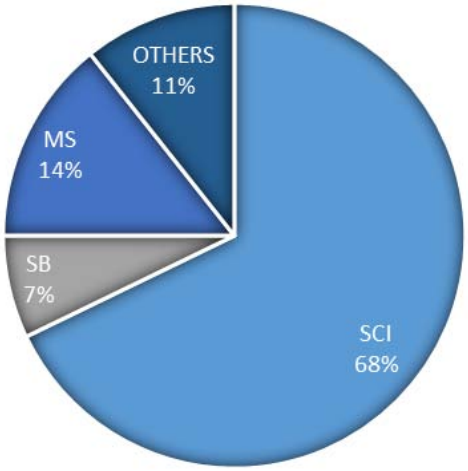

Fig. 3 Causes of NBD in our cohort

Eleven patients (39%) were not satisfied with current bowel management versus 17 (61%) satisfied with current approach. In our sample at baseline twenty-two patients (79%) reported experiencing of problems with their bowel management (bowel accidents, incontinence, cramping pain etc.), whereas 6 patients (21%) reported to be without such problems. During the study no patients reported side effects related to the study device.

Twenty-five (89%) patients reported concomitant therapy all except one patient started the therapy 3 months before the enrolment. They could report more than one reason for concomitant therapy, and the commonest were: pain (65%), depression (32%),

constipation (21%), diabetes (7%) and urinary tract infection (32%), gastric problem (36%) and sexual dysfunction (6%).

All patients underwent a standardised plan of instruction and training to be able to safely perform the transanal irrigation with the Navina Smart system. Of 9 patients (32%) who stopped using Navina Smart system, three (11%) did that for lack of efficacy, two (7%) for leakage of irrigation fluid during the irrigation and four (14%) missed their follow-up visit.

3.1 Utilisation and Compliance

At the end of 4 weeks, 19 (68%) patients were still using the system, undertaking a mean of 5 (± SD 2) procedures per week. Sixteen patients (58%) intubated the rectum just once per procedure to ensure emptying of the bowel; 26% occasionally and 16% regularly undertook a second attempt to clear. Seventy-nine percent of patients used the device independently and only two individuals (7%) needed help with all aspects of irrigation. Table 1 shows the degree of assistance required during the irrigation procedure for the patients completing treatment.

In terms of performance of the device, Navina Smart worked well for patients at both study sites. There were two patients who reported device problems—one was in relation to a single episode of a rectal catheter balloon which failed to inflate and the patient continued to use the system thereafter without problem. The other was a patient who lost confidence in his ability to use the system and wished to discontinue the study due to anxiety.

Two patients in the per-protocol group used another TAI system in addition to Navina Smart during the study period. At the UK site there was one patient who reported subjectively insufficient emptying after Navina Smart use.

3.2 Satisfaction

Satisfaction was assessed in a range of ways. At baseline 40% of our patients reported to be unsatisfied with their bowel management, and whilst the other 60% were “satisfied”, they were willing to change their management hoping for improvement. The most common symptoms at enrolment were constipation (52% ITT analysis), abdominal pain (45% ITT), faecal incontinence (31% ITT) and diarrhoea (18% ITT).

Nineteen of 28 patients (68%) completed the four week study; 50% of the ITT patients included in the study, and 74% of PP (who completed four weeks of the study), expressed a desire to continue to use the Navina Smart System. Eight patients who were not satisfied with their bowel care at baseline were satisfied with the Navina Smart system and wanted to continue the therapy after the study.

Another aspect of satisfaction with bowel care relates to number of times the anal intubation needs to be repeated per episode of irrigation. This fell from 69% who repeated intubation at baseline to 42% at the end of four weeks (PP analysis).

3.3 Perception of Navina Smart System

The Navina Smart system was felt to be practical in 54% of the cohort and not to be practical by 33%.

When asked how the patient perceived the device, 67% out of the ITT cohort expressed that they were

Table 1 Degree of assistance during the procedure of trans-anal irrigation.

Degree of assistance required	ITT (N = 28)
All procedure assistance	2
Setting up the system	2
Filling the water container	1
Catheter insertion	1
Inflating the rectal balloon	2
Catheter withdrawal	0
Other	2

Table 2 Perception for different components of the Navina Smart system.

Category	Easy	Neutral	Difficult	Not known
Deflation of the balloon	75%	7%	11%	8%
Handling the rectal catheter	75%	18%	4%	4%
Product packaging	54%	32%	11%	4%
Unit display/symbols	61%	21%	14%	4%
Water container	79%	14%	4%	4%

satisfied, 33% were not satisfied. In the Table 2 we had shown in details the perception of each component of the Navina Smart system.

4. Discussion

Symptoms of constipation and faecal incontinence are common in patients with diseases of the nervous system, and are collectively termed NBD. When there is loss of visceral sensation in the distal colon conservative therapy with laxatives is usually unsuccessful because the resulting loose stool predisposes to faecal incontinence [5]. TAI (transanal irrigation) has emerged as a valuable alternative treatment and long-term efficacy studies have shown sustained reduction of symptoms [15] and health economic benefits [5]. The particular potential efficacy of TAI relates in that it is both a treatment of constipation and incontinence. Long-term success in patients with NBD is between 55% and 70% [5, 15, 16]. Possible reasons for this variable success rate relate to difficulty with manual dexterity in operating the pump and variation in the day-to-day irrigation regime. Two-thirds of patients perceived the Navina system was satisfactory to use. The packaging and symbols on the display were perceived as the least satisfactory aspects of the Navina system. There were particularly high levels of satisfaction (75%) for the catheter and water container handling. This corresponded to 79% of patients using the device independently, suggesting a relationship between device perception and compliance. A unique feature of this study was that we enrolled patients who wanted to change their current bowel management. Some were not completely satisfied, or dissatisfied with their existing irrigation system, and others had discontinued TAI because of this dissatisfaction and returned to conservative bowel management [5]. Of this population of incompletely satisfied patients, 68% successfully completed four weeks treatment with Navina Smart, and 50% wanted to switch to use the system long-term. The fact that half of the patients wanted to switch systems is a positive indication of the potential utility of the system, especially given that Navina was preferred by 80% of those who were dissatisfied with their existing irrigation regime. Satisfaction with bowel care is a complex concept in neurogenic bowel dysfunction. For some individuals it reflects the absence of symptoms, for some it reflects a mere improvement from previous therapy and for others it reflects a change in quality of life [5-14]. In this study we asked a range of questions to cover these different aspects. Three out of four patients found the Navina system easy to manage, including the innovation of the electronic hand control system to manage the pump. This may relate to the increased potential of independent management of the bowel regime afforded by being able to control the pump without assistance.

Transanal irrigation has been shown to be a safe long term therapy [17], and there were no severe adverse events reported in this study with the use of the irrigation system over 4 weeks. This study was not designed as an efficacy study, but it is noteworthy that 52% of patients felt that their time spent on dealing with their bowel was reduced by using the Navina smart system. It is hypothesised that this may relate to the more predictable irrigation regime that occurred at each occasion with the electronic pump delivering more reproducible irrigation schedule than could be achieved by hand pumping. This difference would be

especially relevant in patients with impaired manual dexterity, as one-third of patients in this study experienced.

There were some limitations with the study. Firstly, we only studied 28 individuals. However, patients with NBD who are experienced with TAI but who are not satisfied with the therapy represent a complex patient group to recruit. They do represent a clinically important group as the alternatives for such patients are rather limited, and usually comprise surgical therapy options. Another limitation is that the study was short-term. That said, this was planned as primarily a tolerability and safety study, not one designed to generate efficacy data. Specific studies on efficacy using Navina in TAI-treatment naive patients are currently underway. Finally, there was no control group in this study, so some of the effects seen may represent regression to the mean. However, this is less likely given these individuals were dissatisfied enough with baseline treatment to enrol for a new formulation of a therapy that they had previously been exposed to. This represents a difficulty to treat group, with less likelihood of spontaneous symptom remission.

5. Conclusions

In conclusion, Navina Smart is a safe novel transanal irrigation system featuring an electronically driven pump. Use of the electronic unit of Navina was perceived as easy by the majority. Patients who were independent in their bowelcare tended to perform best. The study shows how in the short term follow-up the system is well tolerated and perceived as satisfactory in two-thirds of patients, further study with a long term follow-up is planned to evaluate change in neurogenic bowel dysfunction.

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Follow-up Questionnaire

Study Title: Evaluation of a Novel Electronic Transanal Irrigation System—Navina™ Smart

Dear Navina user,

Thank you for taking the time to evaluate the **Navina** Smart system. For us it is very important to have well-documented products with high quality and standard and as "user-friendly" as possible. It is therefore valuable to us that you as a unique user share your experience and opinions with us.

At this visit you will evaluate the Navina Smart system after 4 weeks use.

The questionnaire is self-administrated, however if you are unsure about some of the questions, please ask your study physician or study nurse.

Tick or circle the options given under each question which you believe best describes your situation. When you are asked to answer in more detail, please write as clearly as possible. There are no "right" or "wrong" answers.

Thank you for your participation.

Instructions and training

1. Did you receive adequate instructions and training in how to perform TAI with Navina Smart system?

☐ No

☐ Yes

Please specify the approximate number of hours of training you received: _____

2. Did **you use the Navina Smart system for 4 weeks?**

☐ No (please continue to alternative b-d below)

☐ Yes (please continue to alternative a below)

a. If Yes, please specify the average number of TAI procedures per week:

☐ 1

☐ 2

☐ 3

☐ 4

☐ 5

☐ 6

☐ 7

☐ Other, specify:_____

b. If No, please specify the reason why (tick all that apply):

☐ Difficult inserting catheter or instilling irrigant (water)

☐ No stool evacuated after transanal irrigation

☐ Leakage of irrigation fluid (water) around the catheter during irrigation

☐ Leakage after/between TAI procedure(s)

☐ General discomfort

☐ Handling difficulties

☐ Time-consuming

☐ Lack of efficacy of bowel management

☐ Trauma to anus and/or rectum due to balloon burst

☐ Bleeding

☐ Pain

☐ Autonomic dysreflexia

☐ Other, specify:_____

c. If No, please specify for how many weeks you used Navina Smart:

☐ Less than 1 week

☐ 1 week

☐ 2 weeks

☐ 3 weeks

d. If No, please specify the number of times (in total) you used the Navina Smart system: _____

3. Have you been practicing TAI with any other system since you entered this study?

☐ No

☐ Yes

If Yes, how many times: _____

Handling—before insertion

4. I find preparation of Navina Smart system (connecting tubes, catheter, water container etc.) to be:

☐ Very easy

☐ Easy

☐ Neutral

☐ Difficult

☐ Very difficult

5. I find handling of the water container (filling with water, connecting tubes etc) to be:

☐ Very easy
☐ Easy
☐ Neutral
☐ Difficult
☐ Very difficult

6. I find the preparation and to start up the Navina Smart unit to be:

☐ Very easy
☐ Easy
☐ Neutral
☐ Difficult
☐ Very difficult

7. I find activation of the Navina Smart rectal catheter to be:

☐ Very easy
☐ Easy
☐ Neutral
☐ Difficult
☐ Very difficult

Handling—at insertion

8. I find the Navina Smart unit display/symbols to be:

☐ Very easy
☐ Easy
☐ Neutral
☐ Difficult
☐ Very difficult

9. I find insertion of the Navina Smart rectal catheter to be:

☐ Very easy
☐ Easy
☐ Neutral
☐ Difficult
☐ Very difficult

Handling—balloon inflation

10. Navina Smart—Please specify the set size (1-5) that was appropriate for you?

Size: _____

Handling—rectal catheter ejection

11. Have you experienced any involuntary rectal catheter ejections since you started to use the Navina Smart system?

☐ No

☐ Yes

If Yes, how many involuntary rectal catheter ejections have you experienced? _____

Handling—during irrigation

12. Do you have leakage of irrigation fluid (water) around the catheter during irrigation (when the fluid is instilled)?

☐ No

☐ Yes

☐ Sometimes

If Yes/Sometimes, please specify the reason: _____

Handling – after irrigation

13. I find handling/deflation of the balloon to be:

☐ Very easy

☐ Easy

☐ Neutral

☐ Difficult

☐ Very difficult

14. I find handling of the rectal catheter at withdrawal to be:

☐ Very easy

☐ Easy

☐ Neutral

☐ Difficult

☐ Very difficult

15. I find the product packaging/bag to be:

☐ Very easy

☐ Easy

☐ Neutral

☐ Difficult

☐ Very difficult

TAI procedure—Fluid and stool evacuation

16. Specify the time it takes for fluid and stool to commence/evacuate after catheter withdrawal*?*

☐ Immediately after catheter withdrawal

☐ Not immediately after catheter withdrawal

If not immediately, please specify number of minutes (appr.): _____

17. Do you massage your abdomen or lean forward to assist with emptying?

☐ No

☐ Yes

☐ Sometimes

TAI procedure—after irrigation

18. Do you need to repeat the irrigation procedure during the same visit to the bathroom in order to ensure emptying of the bowel?

☐ No

☐ Yes

☐ Sometimes

TAI procedure—Practical to use

19. I find usability of the Navina Smart system to be:

☐ Very practical

☐ Practical

☐ Neutral

☐ Not so practical, please specify:_____

☐ Not practical, please specify:_____

Perception

20. Please specify how satisfied you are with the Navina Smart system:

☐ Completely satisfied

☐ Satisfied

☐ Neutral

☐ Not satisfied

☐ Not satisfied at all

21. I think the electronic operation of the Navina Smart system saves time during use.

☐ Strongly agree

☐ Somewhat agree

☐ Neither agree nor disagree

☐ Somewhat disagree

☐ Strongly disagree

22. I think the electronic operation makes it easier for me to use the Navina Smart system.

☐ Strongly agree

☐ Somewhat agree

☐ Neither agree nor disagree

☐ Somewhat disagree

☐ Strongly disagree

23. I think the electronic display increases my control as I get continuous feedback on the progress.

☐ Strongly agree
☐ Somewhat agree
☐ Neither agree nor disagree
☐ Somewhat disagree
☐ Strongly disagree

24. I think the electronic device increases my safety as the settings will keep my treatment at the prescribed level.

☐ Strongly agree
☐ Somewhat agree
☐ Neither agree nor disagree
☐ Somewhat disagree
☐ Strongly disagree

Continue using Navina Smart system

25. If possible, would you consider continuing using the Navina Smart system?

☐ No
☐ Yes

Baseline Questionnaire

Study Title: Evaluation of a Novel Electronic Transanal Irrigation System—Navina™ Smart

Current Bowel Management

Changes in bowel function and control may have a considerable impact on the quality of life of individuals with neurogenic bowel disorders. It is therefore important for us to know how satisfied you are with your current bowel management.

At this visit you will answer questions regarding your current bowel management

The questionnaire is self-administrated, however if you are unsure about some of the questions, please ask your study physician or study nurse.

Tick or circle the options given under each question which you believe best describes your situation. When you are asked to answer in more detail, please write as clearly as possible. There are no "right" or "wrong" answers.

Thank you for your participation.

Bowel function

1. How satisfied are you in general with your overall bowel management (e.g. diet, fluid, stool softeners, digital rectal stimulation, TAI)?

☐ Completely satisfied
☐ Satisfied

☐ Neutral

☐ Not satisfied

☐ Not satisfied at all

2. Please specify if you currently are experiencing any type of problem(s) with your bowel management? Tick all that apply:

☐ None

☐ Constipation

☐ Diarrhea

☐ Bowel accidents/faecal incontinence

☐ Abnormal bloating or cramping pain

☐ Other, please specify: _____

3. How much time daily do you spend on your current bowel management (e.g. diet, fluid, stool softeners, digital rectal stimulation, TAI)?

Please specify (appr.): **_____(min)**

4. Please estimate the time spent *sitting on the toilet* for each defecation?

Please specify (appr.): **_____(min)**

Current transanal irrigation (TAI) system

5. How satisfied are you in general with TAI as a therapy?

☐ Completely satisfied

☐ Satisfied

☐ Neutral

☐ Not satisfied

☐ Not satisfied at all

6. Please specify which TAI system you currently use?

☐ Qufora

☐ Peristeen®

☐ Aquaflush

☐ Other, please specify:_____

7. For how long have you been practicing TAI with your current system?

☐ Less than 3 months

☐ 3 months to 1 year

☐ 1-3 years

☐ More than 3 years

8. How often do you practice TAI with your current system?

☐ 1 or more times daily

- ☐ Every second day
- ☐ 2-3 times a week
- ☐ Once a week
- ☐ Less than once a week
- ☐ Other, please specify:_____

TAI procedure—during irrigation

9. **Do you handle the TAI-system yourself (majority of the time)?**

- ☐ No
- ☐ Yes

If No, specify the level of assistance required during the irrigation procedure. Please tick all that apply:

- ☐ I need total assistance/help throughout the TAI procedure
- ☐ Assistance with *Setting up the system*
- ☐ Assistance *Filling the water container*
- ☐ Assistance with *Catheter insertion*
- ☐ Assistance with *Inflating the Rectal balloon*
- ☐ Assistance with *Catheter withdrawal*
- ☐ Other methods, specify: _____

10. How much water do you usually use for each irrigation?

Please specify average number of ml (not an interval): _____ml

11. Do you add anything to the irrigation fluid (water)?

- ☐ No
- ☐ Yes

If Yes, please specify what you add to your irrigation fluid (water)? Tick all that apply:

- ☐ Phosphate
- ☐ Polyethylene glycol
- ☐ Table salt
- ☐ Soap
- ☐ Laxatives
- ☐ Other, specify:_____

TAI procedure—after irrigation

12. Do you need to repeat the irrigation procedure during the same visit to the bathroom in order to ensure emptying of the bowel?

- ☐ No
- ☐ Yes
- ☐ Sometimes