Wellspect®
A REAL DIFFERENCE

INTRODUCTION AND CHECKLIST FOR TRANSANAL IRRIGATION (TAI)

- to adults with Navina Irrigation System

Navina™

Preface

Although TAI is an established therapy, we have found there are still questions and some uncertainties when introducing TAI. We want to increase the awareness and knowledge about TAI, so people who would benefit from the therapy, are given the opportunity to try. For some people, TAI could be the answer for an improved bowel function.

This document should only be seen as a guide. We would like to share the experience we have collected from clinical practice, expert groups and not at least, what we have found in the literature regarding TAI.

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Background

Bowel leakage and chronic constipation are common conditions and have a negative impact of a person's well-being.

The aim of TAI is to improve symptoms and re-establish control of bowel function.[1] Out of 17 studies and 1229 patients, TAI therapy was considered successful in 53% of all cases.

Success rate varied in patient groups with the following symptoms[2]

- constipation 45%
- bowel leakage 47%
- mixed symptoms 59%

When TAI was compared to non-irrigation conservative bowel care, patients using TAI had.[3]

- Fewer complaints of constipation
- Less bowel leakage
- Improved symptom-related quality of life
- Reduced time spent on bowel management procedures

When TAI is established, it gives the user control of when and where to empty the bowel.

TAI will usually only be tried when other conservative methods of bowel management have failed.

The Navina Irrigation System is intended for Transanal Irrigation by instilling water up into the lower part of the colon through a rectal catheter.

Before introducing and teaching TAI, it is important to understand:

- The anatomy and physiology of pelvic floor
- Pelvic floor dysfunction
- The aim of TAI and how it works
- Indications for use
- Contraindications and precautions to TAI
- Available TAI systems and the difference between them

Patient selection and assessment

Diseases/injuries that might cause bowel leakage and chronic constipation are:

- **Neurogenic Bowel Dysfunction (NBD),** e.g. Spinal Cord Injury, Spina Bifida, Multiple Sclerosis and Parkinson's Disease
- **Functional Disorders,** e.g. constipation incl. evacuations difficulties and slow transit constipation
- **Pelvic Floor Dysfunctions,** e.g. rectal damage after childbirth and prolapse
- **Post-surgical situations,** e.g. LARS

Initiation of TAI will primarily be on clinical judgement based on individual prerequisites. However, careful patient selection, supervised training and follow up are considered as essential factors to achieve an optimal result and long-term adherence of TAI[4].

The clinician is responsible for the assessment and to ensure that the patient fulfills the criteria for TAI and that no contraindications are existing.

It is also the responsibility of the clinician to perform pre-assessments according to clinical and local practice.

The clinician should also discuss the medication and how to proceed with this, e.g.

Continue to use any necessary medication, for example:[5]

Laxatives:

- Continue to take laxatives when using TAI
- When regime/routine is established assess if reduction of laxatives is required

Antidiarrhea e.g. Loperamide:

- Continue to take antidiarrhea medication when using TAI (if required)
- When regime/routine established assess if reduction of antidiarrhea medication is required

If the patient is constipated, an initial clearance of the bowel must be performed before starting the irrigation treatment.

Checklist

- ☐ Discuss the reason for initiation, e.g. failure of conservative therapy
- ☐ Identify any criteria that would contraindicate the use of TAI

Do NOT use Navina Irrigation System if you have one or more of the following:

- Known anal or colorectal stenosis
- Active inflammatory bowel disease
- Acute diverticulitis
- Colorectal cancer
- Ischemic colitis
- You are within three months of anal or colorectal surgery
- You are within 4 weeks of previous endoscopic polypectomy
- You are pregnant

As the list may not be exhaustive, you will always need to consider individual user factors as well.

- ☐ Follow up advise given from the clinician about medication
- ☐ Explain the anatomy and function of the bowel
- ☐ Explain the therapy and how it works
- ☐ Explain the individual advantages with TAI
  - Restores bowel function, which increases the overall well-being
  - If performed every day, or every second day, the bowel stays empty until the next irrigation
  - Time saving
- ☐ Discuss expectation and set a realistic goal together with the patient
  - Allow 4-12 weeks to achieve good adherence
- ☐ Obtain informed consent
  - Follow local policy and document in the patient's medical record
- ☐ If applicable: Ask patient to complete NBD Score

Teaching

Whenever possible, the goal is to teach the patient to perform the irrigation independently.

☐ **Show the product and explain why this product is chosen**

- Navina Smart/Navina Classic
- Rectal catheter or cone

  If a rectal catheter will be used, explain the aim of the balloon, i.e. it holds the catheter in place and creates a seal preventing the water from leaking

☐ **Show Wellspect animation/s and handing out written information about the therapy**

☐ **Demonstrate the product – Instructions for Use must always be followed**

- How to assemble the product
- How to use the water container

  – Lukewarm water, 36-38° C

  – Fill to the upper mark of the water container

- How to activate the hydrophilic surface of the rectal catheter/cone
- Insertion of the catheter and balloon inflation

  The balloon size is highly individual

  If Navina Smart is used, it is not uncommon to start with size 2 (40,5 ± 5 mm) or 3 (49 ± 5 mm)

  If Navina Classic is used, 2 pumps could be a good to start with.

  ***Note:** Never use more than 5 pumps when you are using the Navina regular catheter and never more than 2 pumps when the Navina Small catheter is used.*

- Instillation of water

  Water amount to be instilled is highly individual and should always be recommended from the healthcare professional. However, an amount of 300-700 ml is common to start with.

  Navina Smart: One example is to start with setting 2 or 3, where 2 corresponds to 200 ± 50 ml/min and 3 corresponds to 350 ± 50 ml/min.
  The amount of water instilled, can be followed on the Navina Smart control unit. The water flow is always stopped when the button is released, this gives control during the procedure.

Navina Classic: The water instillation speed, varies depending on how fast you pump. Pumping with full capacity every 5 to 10 seconds gives a flow rate of approximately 300 – 500 ml/min.

Use the scale on the water container to check the amount of water instilled.

- Show how to deflate the balloon

  The catheter should not be removed before the balloon is completely deflated.

- Evacuation. The evacuation time is individual and can vary from one day to another.

☐ Advise about TAI frequency

- Advise to perform TAI daily in the beginning and should then be reduced to alternate days where possible after approximately 10-14 days.[4]

☐ Inform about Wellspect's support program

- A personal contact is provided
- Regularly support and advice

☐ Recommend the patient to use a bowel diary, or Navina Smart App

- Will make it easier to follow the progress and help to identify optimal performance and outcome

☐ If Navina Smart is used: Inform about the Navina Smart app

If needed: Download the Navina Smart app

☐ Inform about the prescription process and how to order new supplies

☐ Document the therapy start in patient's medical record according to local policy

Tips

- If possible, recommend performing the irrigation 20-30 min after food intake to take advantage of the gastrocolic response.
- If the bowel does not start to empty on its own, relax for 10-15 minutes and then try to lean forward and aside, cough, perform abdominal massage or move the upper body to start the emptying process.
- Ensure a comfortable position on the toilet (with a footstool if feet do not touch the ground) to promote pelvic floor relaxation.

Follow up and adherence

Follow up is considered as an essential factor to achieve an optimal result and long-term adherence of TAI.[4]

The aim of the follow up process is to identify optimal performance and outcome of the irrigation. If the patient reports specific problems or symptoms, or if there is inadequate efficacy, you will be able to advise tailoring the regime to the patient.

Suggestion of follow up frequency[5]

- 1-2 weeks by phone after commencing TAI
- 4 weeks by phone after commencing TAI
- 6-8 weeks by phone after commencing TAI
- 3 months by phone (or in clinic if preferred) after commencing TAI

At the follow up calls, we suggest asking the following questions:

- ☐ **Overall perception**
- ☐ **Any experienced changes, both positive and negative, since last time**
- ☐ **Any experience of leakage/constipation**
- ☐ **Any changes in medication since last time**
- ☐ **Follow up of bowel diary,** e.g. in the Navina Smart App
- ☐ **If NBD score was used prior therapy start, ask patient to complete it again. Any change?**
- ☐ **Follow up of prescription. Does the patient have enough of Navina supplies?**

If the patient is satisfied, continue as is. If problems or symptoms described below occur, follow recommendations for each problem or symptom.

Troubleshooting[4]

Bleeding

- A small amount of bleeding is to be expected, but more copious or regular bleeding requires further investigation
- Haemorrhage with or without pain suggests a possible bowel perforation*, which should be assessed as a potential medical emergency

Pain

- If cramps, discomfort or pain occur while instilling the water, pause the instillation and continue more slowly once the discomfort has subsided
- Ensure that the water is warm enough, around 36–38° C
- Reduce the size of the balloon
- If pain is severe/persistent stop irrigating – possible bowel perforation* – assess as a potential medical emergency

Leakage of water around the catheter/cone

- Ensure catheter/cone is properly located
- Ensure water temperature 36-38° C
- Increase the size of the balloon
- Instill the water more slowly initially and increase gradually
- Check for and treat constipation

Irrigant is not expelled

- Check the equipment
- Repeat irrigation
- Ensure patient is adequately hydrated
- Assess for constipation and treat if necessary

No stool is evacuated after transanal irrigation

- Repeat irrigation or split the irrigation into two consecutive episodes, 10–15 min between episodes, using half the irrigant each time
- Consider use of laxatives
- Check for constipation and treat as required
- Ensure the patient is well hydrated
- No stool may be present if a good result was obtained at last irrigation; if this happens regularly consider reducing frequency of irrigation
- If no stool for several days, suspect constipation/impaction, assess and treat accordingly

**Bowel perforation is very rare, 1 out of 500 000 irrigations, yet extremely serious complication of TAI*

Bowel leakage between irrigations

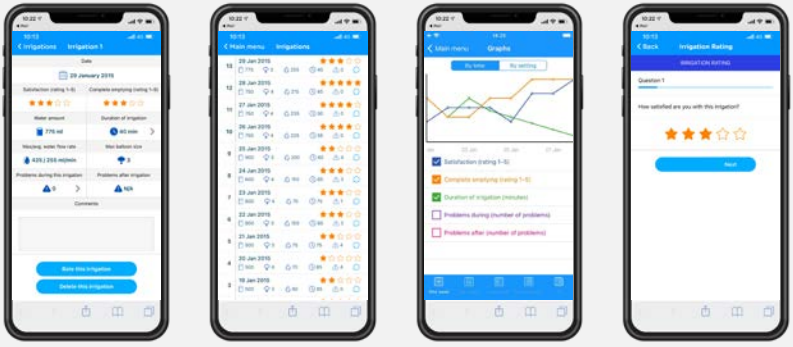
- Increase volume of water by small increments (100ml) until satisfactory evacuation achieved with no bowel leakage
- Split the irrigation into two consecutive episodes, 10–15 min between episodes, using half the irrigant each time
- Increase frequency of transanal irrigation
- Consider laxative use

Leakage of water between irrigations

- Ensure patient allows sufficient time on toilet following transanal irrigation
- Reduce or decrease amount of water instilled
- Split the irrigation into two consecutive episodes, 10–15 min between episodes, using half the irrigant each time

To read more

- Instructions for Use
- Wellspect.com



Follow your improvements in Navina Smart app.

Available on the App Store

Get it on Google play

Navina Irrigation System
The only irrigation system with electronic or manual control

Navina Irrigation System consists of Navina Classic, which is manually controlled and Navina Smart, which has an electronic control unit. Navina Smart is the only electronic solution for Transanal irrigation (TAI), also known as bowel irrigation, with an app for follow-up and monitoring the therapy.

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References

1. Emmanuel. Spinal Cord. 2010. 48(9): p. 664-673
2. Christensen and Krogh. Scand J Gastroenterol. 2010. 45: p. 517-527
3. Christensen et al. Gastroenterology. 2006. 131(3): p. 738-747
4. Emmanuel et al. Spinal Cord. 2013. 51(10): p. 732-738
5. Emmanuel et al. Gastrointestinal Nursing. 2019. 17(7): p. 24-30

At Wellspect we develop innovative continence care solutions that improve quality of life for people with bladder and bowel problems. We inspire our users to build self-confidence and independence as well as good health and well-being. We have been leading the industry for over 40 years with our product brands LoFric® and Navina™. We always aim to minimize the environmental impact of our products and passionately strive to become climate neutral. We work together with users and healthcare professionals to improve clinical outcome in a sustainable way, now and for the future.

Wellspect. A Real Difference.

For more information about our products and services, please visit Wellspect.com.
Join the conversation on LinkedIn, Twitter, Facebook and Instagram.

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Navina Irrigation System

Intended use

Navina Irrigation System is intended for Transanal Irrigation by instilling water up into the lower part of the colon through a rectal catheter.

Indications

The Navina Irrigation System is indicated to help adults and children from 3 years who suffer from fecal incontinence, chronic constipation, and/or time consuming bowel management. By instilling water up into the lower part of the colon, the peristaltic muscles in the bowel can be triggered and start to evacuate the content of the lower colon and rectum.

Contraindications

Do NOT use Navina Irrigation System if you have one or more of the following:

- Known anal or colorectal stenosis
- Active inflammatory bowel disease
- Acute diverticulitis
- Colorectal cancer
- Ischemic colitis
- You are within three months of anal or colorectal surgery
- You are within 4 weeks of previous endoscopic polypectomy
- You are pregnant

As the list may not be exhaustive, healthcare professionals will always consider individual user factors as well. Before use see Instructions for Use.

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