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# NAVINA™ SMART – A NEW OPTION FOR TRANSANAL IRRIGATION IN TREATMENT-REFRACTORY NEUROGENIC BOWEL DYSFUNCTION

Hypothesis / aims of study

Constipation and faecal incontinence have a major negative effect on quality of life in patients with neurological disease. Transanal irrigation (TAI) is established as a key therapeutic option when conservative measures fail. However, up to 50% of patients do not respond to TAI, and in such situations, the only therapeutic options are more invasive implants or surgery.

Study design, materials and methods

Twenty-eight patients (17 female, mean age 52 range 24-73) with neurogenic bowel disorder (NBD) were recruited from two specialist centres (19 with spinal cord injury, 2 spina bifida, 4 Multiple Sclerosis and 1 each following spinal surgery, tumour and cauda equina syndrome). All participants were experienced with TAI, used at a frequency of at least 2 times/week. Patients were trained to use Navina™ Smart, a system of irrigation controlled by an automated balloon inflation and water pump, and followed up for 4 weeks to monitor patient satisfaction, perception and compliance using a Patient Reported Outcome questionnaire. There were two telephone contacts at week 1 and 2. Safety of the Navina™ Smart system was also assessed by questioning and self-report.

Results

19 patients (68%) completed the 4 weeks of TAI per protocol (PP), whilst 9 discontinued prematurely (3 for lack of efficacy, 2 for leakage of irrigation fluid, 1 trip abroad and 3 missing). Of those 19, 14 (74%) reported a desire to continue with TAI using Navina™ Smart, representing 50% of the intention to treat (ITT) population; 12/19 (63% of PP and 14/28 of ITT) reported complete or adequate satisfaction with therapy. At baseline 10/19 were neutral or not satisfied with existing TAI, 8 of these 10 would consider continuing with Navina™ Smart.
A majority (81 %, 22 of 27 available patients) found the preparation and handling of the system, and the components, to be easy or very easy.

Interpretation of results

Three-quarter of patients who completed the study with Navina wanted to continue use of the product. This was especially true in a group who were dissatisfied with their existing TAI, a challenging group to manage given the invasive alternatives. This indicates that Navina Smart is a viable option in TAI treatment. A similar majority found the Navina system easy to handle, which is an indication that an electronic device may be an advantage from a patient's perspective. The heterogeneity and small patient number mean limited conclusions can be drawn about response to Navina in different patient subtypes.

Concluding message

From this first clinical study of Navina™ Smart System we conclude that handling was easy for 81% of patients and, that there were no safety concerns. The device was well accepted and effective in 74% of patients that continued for 4 weeks. This is especially relevant in a patient group, such as included here, who were unhappy with their existing TAI treatment.

Disclosures

**Funding:** Clinical study fully sponsored by Wellspect Healthcare **Clinical Trial:** Yes **Registration Number:** clinicaltrials.gov NCT02709395 **RCT:** No **Subjects:** HUMAN **Ethics Committee:** East of England - Cambridge East Regionala etikprövningsnämnden Stockholm **Helsinki:** Yes **Informed Consent:** Yes