

Efficacy of Peristeen transanal irrigation system for neurogenic bowel in the pediatric population: Preliminary findings

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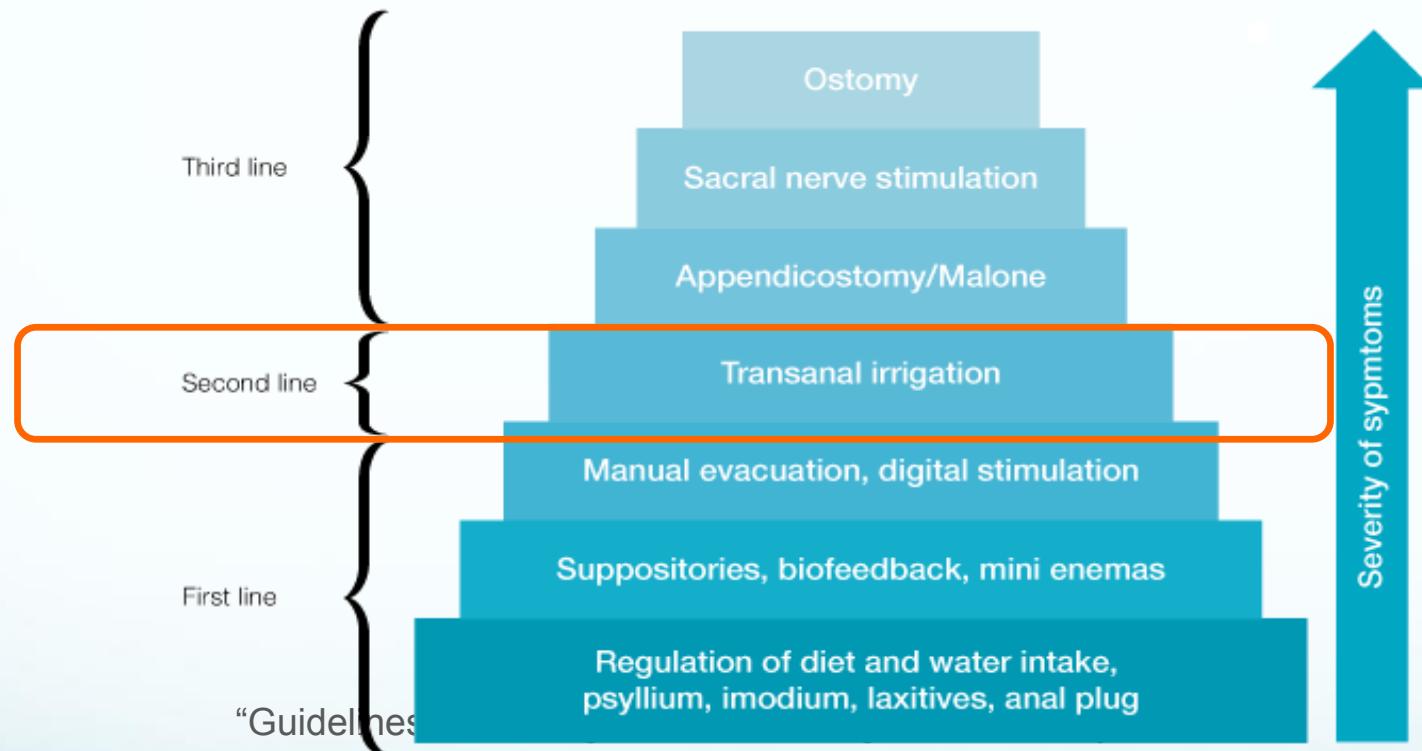
Purpose

To evaluate the efficacy of Peristeen®
in pediatric patients with neurogenic
bowel.

Background

- Peristeen® was approved by the FDA for use in the US in 2012
- Peristeen® Anal Irrigation System is an FDA Class II cleared trans-anal irrigation system
- Peristeen® is a unique enema system that uses a pump rather than gravity to instill water as a colonic irrigant and utilizes balloon occlusion of the rectum.

Clinical Indication of TAI/Peristeen®

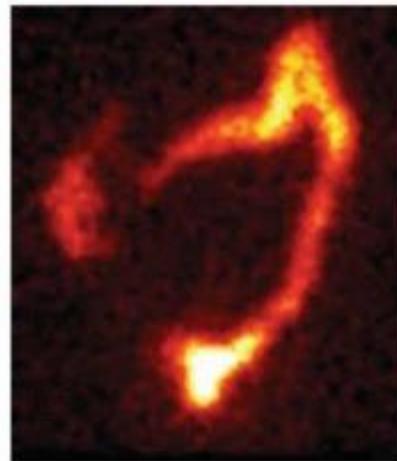


Individuals with Central Neurological Conditions" 2012

A previous study by Christensen et al showed these results

Feces present in descending colon and rectum before TAI

Before defaecation



After defaecation



Descending colon and rectum empty after TAI

Christensen, Olsen, Krogh, Bacher & Laurberg (2003)

Peristeen® helps patients:

- Regularly empty their bowels when they choose
- Prevent stool accidents and constipation
- Reduce the possibility of involuntary stool leakage
- By greatly improving the quality of life



Includes:

- Screw top
- Bag

- Pump & control unit
- Catheters with balloon



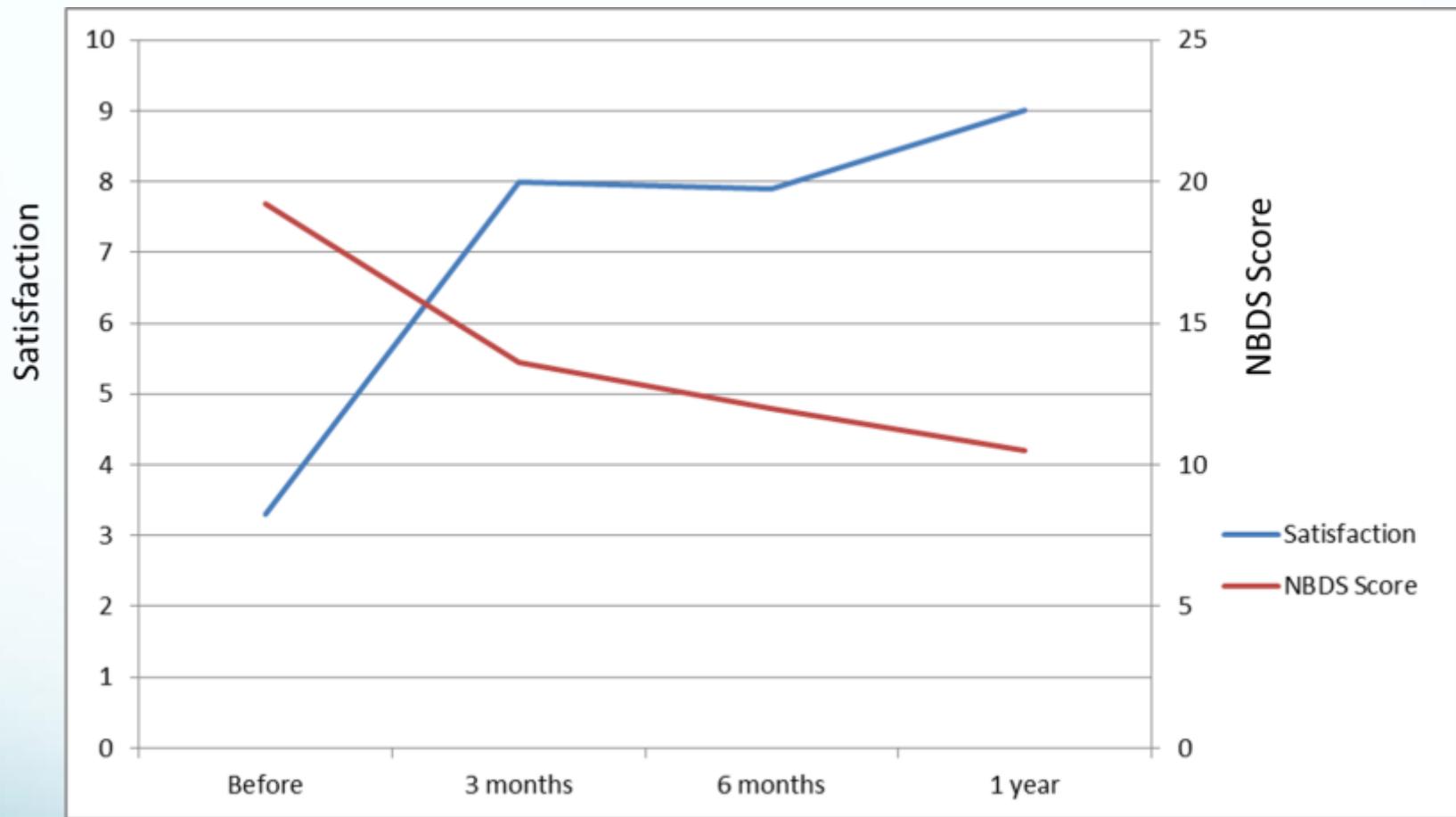
- The catheter is inserted into the rectum.
- The balloon is inflated.
- The water is pumped in.
- The balloon is deflated.
- Water and stool are evacuated.

Methods

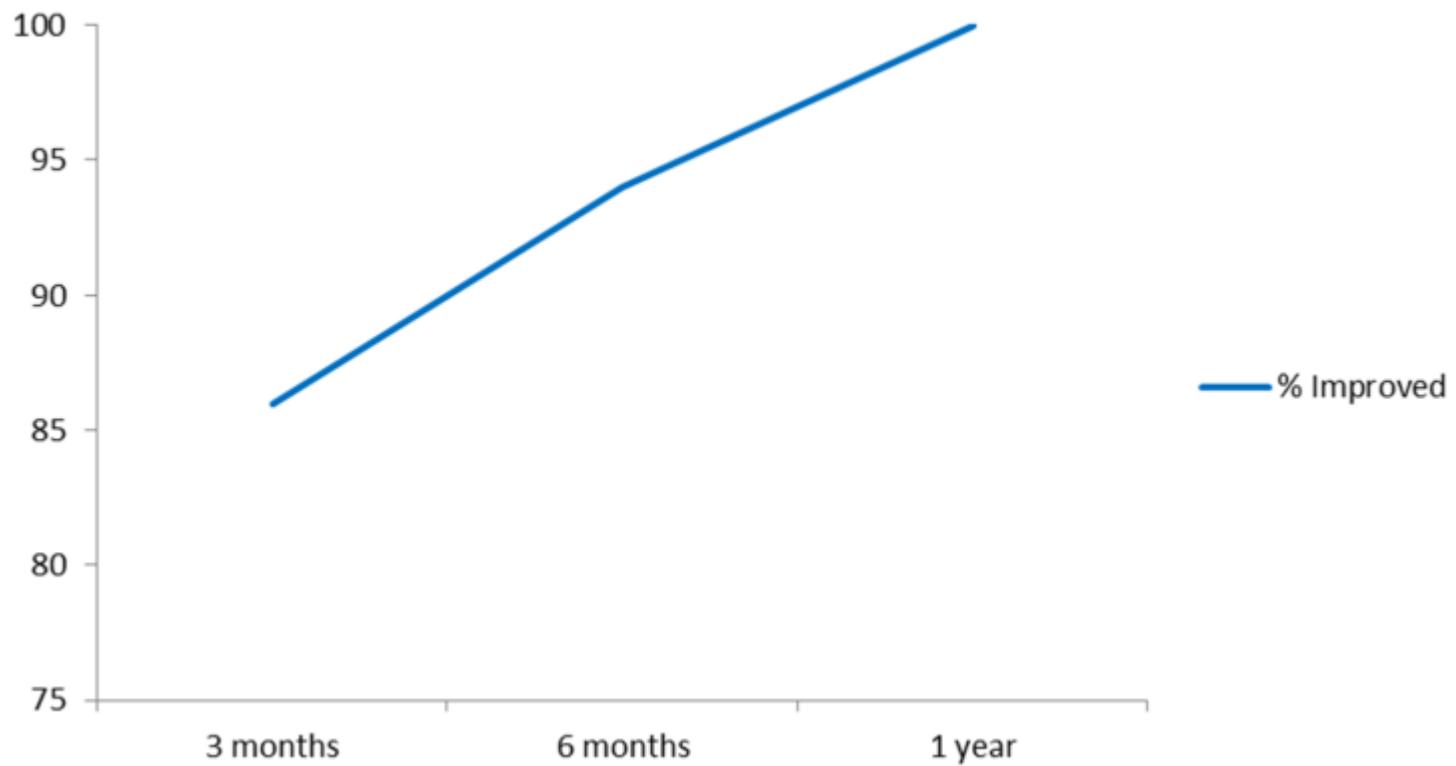
- **Study population:**
 - All pediatric patients with neurogenic bowel referred for failure of one or more other treatment modalities.
 - No patients excluded.
- **Assessment:**
 - Chart review for detailed assessment of primary diagnosis and prior treatment modalities.
 - Prospective data acquisition
 - upon enrollment, and at 3, 6 and 12 months
 - Neurogenic Bowel Dysfunction Scoring Tool (NBDS)
 - Likert Scale for patient/family satisfaction

Results

- Primary diagnosis include:
 - 33 patients with Spina Bifida
 - 6 patients with Cerebral Palsy
 - 2 patients with Tethered Cord
 - 1 patient with Transverse Myelitis, Imperforate Anus, Muscular Dystrophy, & other diagnosis of spine (Tarlov cysts)
- 62 patients referred (as of 8/22/16)
- 45 patients approved received training
- All patients failed 1 or more bowel programs, including:
 - 4 patients with prior ACE procedures
 - 22 patients with prior enema programs
 - 22 patient with oral agents only
- NBDS scores decreased in:
 - 64% in first 3 months of using Peristeen
 - 88% in first 6 months of using Peristeen
 - 100% of patients failing ACE responded to Peristeen
- 3 patients did not respond and underwent ACE procedure
- Patients with prior ACE (n=4) had 100% success with Peristeen®
- 7% (n=3) of patients failed treatment with Peristeen®



% NBDS Improved



Benefits of Peristeen®

- Initially Peristeen® clean out is done every day, but most patients get such good clean out that they can eventually go to every other day
- Peristeen® significantly reduces the amount of time spent for bowel program (most patients take 30 minutes or less including set-up)
- Most patients can reduce or eliminate bowel medications that they are taking once Peristeen® is established

Conclusions

1. Peristeen is an effective treatment option for pediatric patients with neurogenic bowel even if prior modalities have failed.
2. Efficacy improves over time.

X-ray taken day at beginning of Peristeen® teaching



Clean out done & Peristeen done daily and then...

X-ray taken 5 days after Peristeen started



Questions



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