

Clinical Evidence of Peristeen® in Low Anterior Resection Syndrome (LARS)

Introduction

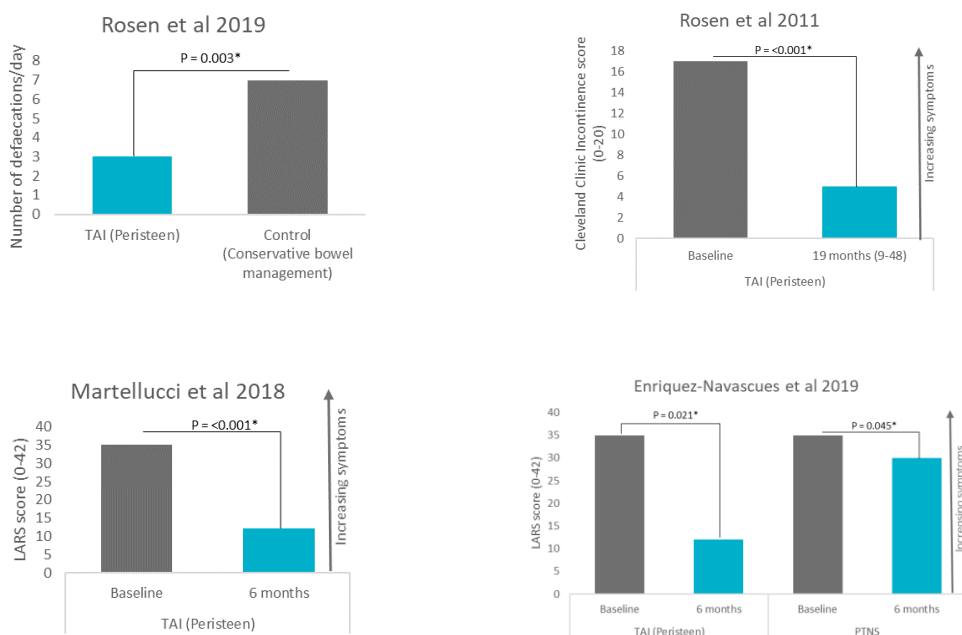
Colorectal cancer is the second and third most common type of cancer in women and men. Surgical resection is often indicated, and anterior resection techniques may allow patients to keep their anal sphincter. However, functional problems arising after surgery lead to a constellation of symptoms defined as low anterior resection syndrome (LARS) in up to 80 % of patients¹. Symptoms of LARS include faecal incontinence or urgency, frequent or fragmented bowel movements, emptying difficulties, and increased intestinal gas.

Four clinical studies have investigated transanal irrigation (TAI) with Peristeen as an alternative to conservative bowel management (CBM) and posterior tibial nerve stimulation (PTNS) for treatment of LARS. TAI has been successfully used to treat neurogenic bowel dysfunction in the spinal cord injured population for more than 10 years.

Clinical studies overview

Study name	Rosen et al 2019 ²	Enriquez-Navascues et al 2019 ³	Martellucci et al 2018 ¹	Rosen et al 2011 ⁴
Study design	Randomized controlled trial	Randomized controlled trial	Prospective interventional study	Prospective interventional study
Comparator	TAI vs CBM	TAI vs PTNS	TAI	TAI
Study size	37	27	36	14
Intervention timeline	3 months	6 months	9 months	Mean 19 months (9-48)
Primary endpoint	Maximum number of defaecation episodes during daytime at 1 month after ileostomy closure	Reduction of at least one LARS grade in at least 50% of patients	LARS score	Cleveland Clinic Incontinence score
Secondary endpoints	Maximum number of defaecation episodes per night, Wexner score, LARS score and SF-36	Vaizey score, EORTC QLQ-C30 and VAS score	SF-36 and MSKCC BFI	SF-36 and Rockwood (ASCRS) QOL
Conclusion	Prophylactic TAI led to a significantly better functional outcome compared with supportive therapy for up to 3 months.	Both treatments improved the LARS score in this study, but this was only significant in the TAI group.	TAI appears to be an effective treatment for LARS and results in a marked improvement of continence and quality of life.	TAI is an effective treatment of anterior resection syndrome and results in a marked improvement of the continence score and QOL

Results from primary endpoints



Conclusion

The four studies demonstrate that treatment with TAI (**Peristeen, Coloplast**) leads to significant improvements in continence and quality of life for patients with LARS in comparison to conservative bowel management and posterior tibial nerve stimulation.

1 Martellucci, J. et al. Role of transanal irrigation in the treatment of anterior resection syndrome. Tech. Coloproctol. 22, 519–527 (2018).

2. Rosen, H. R. et al. Randomized clinical trial of prophylactic transanal irrigation versus supportive therapy to prevent symptoms of low anterior resection syndrome after rectal resection. BJS Open bjs5.50160 (2019). doi:10.1002/bjs5.50160

3. Enriquez-Navascues, J. M. et al. A randomized trial comparing transanal irrigation and percutaneous tibial nerve stimulation in the management of low anterior resection syndrome. Color. Dis. 1–7 (2019). doi:10.1111/codi.14870

4. Rosen, H., Robert-Yap, J., Tentschert, G., Lechner, M. & Roche, B. Transanal irrigation improves quality of life in patients with low anterior resection syndrome. Color. Dis. 13, (2011).