

# Clinical Evidence of Peristeen® in pediatric patients with bowel dysfunctions

## Introduction

Neurological and functional diseases are common causes of severe constipation that causes soiling and faecal incontinence, if not properly managed. Here three studies are presented, aiming at evaluating the efficacy and effects on the quality of life (QoL) among pediatric patients with anorectal malformation (ARM), congenital or acquired spinal cord lesions (SCLs) and spina bifida (SB) by performing transanal irrigation with Peristeen® (PTAI).

## Clinical studies overview

First author, year	Midrio et al 2015 <sup>1</sup>	Ausili et al 2018 <sup>2</sup>	Märzheuser et al 2016 <sup>3</sup>
Study type	Multicentric clinical trial	Multicentric clinical trial	Monocentric clinical trial
Participant Centers	<ul style="list-style-type: none"> <li>University Hospital, Padua</li> <li>Bambino Gesù Children Hospital and Research Institute, Rome</li> <li>University Medical School, Rome</li> <li>Second University of Naples</li> <li>Pediatric Hospital, Parma</li> <li>Vittore Buzzi Pediatric Hospital, Milan</li> <li>Annunziata Hospital, Cosenza</li> <li>Fondazione Ca'Granda – Ospedale Maggiore Policlinico, Milan</li> </ul>	<ul style="list-style-type: none"> <li>Catholic University Medical School, Rome</li> <li>Catholic University of Sacred Heart, Rome</li> <li>Università della Campania Luigi Vanvitelli, Naples</li> <li>Fondazione IRCCS Ca' Granda-Ospedale Maggiore Policlinico, Milan</li> <li>Cà Foncello Regional Hospital, Treviso</li> <li>Bambino Gesù Children Hospital and Research Institute, Rome</li> <li>Pediatric Hospital, Parma</li> <li>Vittore Buzzi Pediatric Hospital, Milan</li> </ul>	Charité University Hospital, Berlin
Patient condition	ARM, SCL	ARM, SB	ARM
Inclusion criteria	<ul style="list-style-type: none"> <li>6-17 years old</li> <li>weight above 20 kg</li> <li>unsatisfactory bowel management</li> </ul>	<ul style="list-style-type: none"> <li>6-17 years old</li> <li>weight above 20 kg</li> <li>unsatisfactory bowel management</li> </ul>	<ul style="list-style-type: none"> <li>4-18 years old</li> <li>Impaired sphincter function</li> </ul>
Study size	83 pz ARM: 31 pz, 10 pz SCL: 15 pz, 22 pz	74 pz ARM: 25 pz, 11 pz SB: 14 pz, 24 pz	40 pz
Endpoints	<ul style="list-style-type: none"> <li>Bristol scale</li> <li>CHQ-PF50 (6–11 years old)</li> <li>SF36 (12-17 years old)</li> </ul>	<ul style="list-style-type: none"> <li>Bristol scale</li> <li>CHQ-PF50 (6–11 years old)</li> <li>SF36 (12-17 years old)</li> </ul>	<ul style="list-style-type: none"> <li>Control for soiling</li> <li>Time needed for irrigation</li> </ul>
Assessment timeline	T0 T1= 3 months	T0 T1= 3 months T2≥ 24 months	T0 T1= 6 or 12 months T2= 2, 3, 4 years

## Results

Endpoints	Timeline	Midrio et al 2015 <sup>1</sup>		Ausili et al 2018 <sup>2</sup>			Märzheuser et al 2016 <sup>3</sup>		
		T0 % (ARM/SCL)	T1 % (ARM/SCL)	T0 % (ARM/SB)	T1 % (ARM/SB)	T2 % T1 % (ARM/SB)	Before PTAI (median)	While using PTAI (median)	
Constipation		69/92.7	25.6/41.5	81%	33%	45%			
Faecal Incontinence		50/39	18.6/9.8	45%	14%	21%			
Bristol scale: Type 1-2 Type 4-5		47.5/77.5	0/2.5	47/77	0/3	11/19			
		30/2.5	87/82	30/3	87/82	65/50			

  

QoL Questionnaire items	Condition	Midrio et al 2015 <sup>1</sup>		Ausili et al 2018 <sup>2</sup>	
		ARM	SCL	ARM	SB
CHQ-PF50: Social limitations (T0-T1)		-34.4	-24.3	-34.4	-24.3
SF36: Physical functioning (Increase T0 to T1)		17.5	22.7	17.5	22.7

  

Endpoints	Timeline	Before PTAI (median)	While using PTAI (median)
		Soiling grade 3 (Krackenbeck)	40
Time needed for irrigation (min/d)		65	30

## Conclusion

The studies showed that improvements in constipation, faecal incontinence and QoL were achieved in pediatric patients with ARMs, SCLs and SB in the short and mid-long term by using PTAI.

1.P. Midrio, et al. Colorectal Disease 2015;18: 86-93. 2.E. Ausili, et al. Child's Nervous System 2018; 34: 2471–2479. 3.S. Märzheuser, et al. Eur J Pediatr Surg 2016; 26(02): 186-191.

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