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Randomized Clinical Trial

Transanal irrigation for low anterior resection syndrome treatment: international multicentre randomized clinical trial

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Abstract

Background: Long-term bowel dysfunction can impact a significant proportion of patients following anterior resection. The aim of this study was to assess the efficacy of transanal irrigation (TAI) to treat low anterior resection syndrome.

Methods: Adults (≥ 18 years) with major low anterior resection syndrome (score > 30) at least 12 months after low anterior resection were enrolled at four European centres. Eligible patients were randomized 1 : 1 using block randomization to the TAI group or best supportive care group. The primary endpoint was the feasibility of TAI measured by treatment adherence or switch of therapy. Secondary endpoints included bowel function, quality of life and study-specific patient satisfaction questions. Outcome evaluators and the statistical team were blinded to allocation, whereas participants and caregivers were unblinded.

Results: Forty-one patients were randomized, of which 40 (19 TAI; 21 best supportive care) completed follow-up; 1 patient in the TAI group was excluded due to fistula surgery. At 12 months, low anterior resection syndrome (median 3 (range 0–39) *versus* 36 (2–42); $P < 0.001$) and Wexner scores (median 0 (0–15) *versus* 13 (4–20); $P < 0.001$) were significantly lower in the TAI group compared with the control group. The Measure Yourself Medical Outcome Profile score was lower in the TAI group after 3 months (median 2 (0–11) *versus* 11 (7–12); $P < 0.001$). In addition, patients in the TAI group achieved higher Memorial Sloan Kettering Cancer Center Bowel Function Instrument scores after 12 months (median 89 (37–90) *versus* 39 (28–61); $P < 0.001$). Adherence was high, with 15 (75%) maintaining daily irrigation, and patient satisfaction measures favoured TAI. Two mild procedure-related adverse events (tenesmus, dizziness) were reported.

Conclusions: This randomized clinical feasibility study confirms that TAI is feasible and has high acceptability for patients. It leads to better functional outcomes and improvements in quality of life compared with the best supportive care for patients with low anterior resection syndrome.

Registration number: NCT05920681 (http://www.clinicaltrials.gov).

Introduction

Rectal resection with primary anastomosis is currently the standard for the treatment of rectal cancer and is usually combined with neoadjuvant treatment (chemoradiotherapy or total neoadjuvant treatment) in cases of locally advanced rectal cancer[1]. However, preoperative chemoradiotherapy, vascular dissection, and resection of the rectum with the mesorectum can result in long-term bowel dysfunction in a significant proportion of patients[2]. Up to 80% of patients experience postoperative symptoms such as faecal urgency, frequent bowel movements, tenesmus, stool fragmentation, and incontinence, collectively known as low anterior resection syndrome (LARS)[2,3]. LARS may persist for a long time and almost 50% of patients report defaecation symptoms 5 or more years after surgery[4,5].

Current treatment approaches for LARS vary widely[6]. The initial approach typically involves dietary changes and medications to control bowel movements and improve stool consistency[7]. For patients who do not respond adequately, pelvic floor rehabilitation, biofeedback therapy, and sacral nerve stimulation may be recommended[7]. Despite the availability of supportive and rehabilitative measures, there is no curative treatment for LARS[6], and studies of these interventions are often limited to small participant numbers[8–11]. The need for

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innovative therapies remains, as patients with severe LARS continue to suffer from a reduced quality of life (QoL) despite these interventions[7].

Transanal irrigation (TAI) is a promising option for managing LARS, especially in patients who do not respond to conservative measures[12–17]. This technique involves the introduction of water into the bowel through the anus, which promotes efficient evacuation of the rectum and left colon[18]. TAI can significantly improve bowel function by reducing stool frequency, promoting complete evacuation, and minimizing episodes of urgency and incontinence[12–15]. The potential of TAI to relieve LARS symptoms and improve QoL has generated interest in its broader application[12–15].

The primary aim of this multicentre, randomized clinical study was to evaluate the feasibility of TAI in patients who have undergone rectal resection for cancer. The study specifically assessed treatment adherence to TAI, switch of therapy (whether patients discontinue or change treatment), and QoL improvements compared with best supportive care.

Methods

The study was approved by the Vilnius Regional Biomedical Research Ethics Committee (No. 2023/5-1513-974) and local Institutional Review Boards in other countries (see *supplementary material* for details). The main researcher and the institution conducting the study created the conditions for the control of the biomedical study, conducted audits, ensured ethical supervision, and performed inspections as required by the laws and legal acts of the Republic of Lithuania regulating the conduct of biomedical studies. This study was conducted in accordance with the CONSORT guidelines, and a completed CONSORT checklist is provided in the *supplementary material*. The study period was from May 2023 to May 2025 (1 year of patient inclusion and 1 year for follow-up). The outcomes registered on ClinicalTrials.gov reflect the initial protocol. During the study, prior to final analysis, the primary endpoint was refined to focus on feasibility (treatment adherence and therapy switch), which was considered more appropriate for evaluating real-world implementation of TAI.

Trial design

This multicentre, randomized feasibility clinical trial enrolled patients from four European centres (UK, Portugal, and two Lithuanian centres). Eligible participants for this study were adults (≥ 18 years) who had undergone low anterior resection (robotic, laparoscopic, or open) with an anastomosis up to 5–7 cm from the anocutaneous line when assessed with digital rectal examination and/or endoscopy, and at least 12 months having passed since the operation or the closure of the ileostomy (if formed). Participants were required to exhibit major LARS, with a score greater than 30 points, indicating significant bowel dysfunction[20], and to have the mental and physical ability to perform TAI. Informed consent was obtained from each patient before enrolment. Exclusion criteria included anastomotic leak or stenosis, as confirmed clinically on examination and/or on contrast enema, any active tumour recurrence or progression, pregnancy, a diagnosis of inflammatory bowel disease, a side-to-end anastomosis, the need for palliative care, or an inability to perform the TAI procedure independently.

Eligible patients were randomized into two groups equally using block randomization by the main researcher (blocks of four and a 1:1 ratio were used) by the hospital Principal Investigator (PI) using an online-based method (randomization.com). The intervention group received TAI and the control group received best supportive care. During the study, subjects' names were replaced with unique codes used in all documents except the informed consent form. Only the main researcher and their representatives had access to identifiable data, whereas the statistical team remained blinded to group assignments.

The primary endpoint of the study was the feasibility of TAI measured by treatment adherence (patients continuing TAI as prescribed) or switch of therapy (patients discontinuing or changing treatment).

Secondary endpoints were:

- Bowel function outcomes measured using the LARS score, Wexner score (faecal incontinence severity), and Memorial Sloan Kettering Cancer Center Bowel Function Index (MSKCC BFI) score.
- QoL assessment using the Measure Yourself Medical Outcome Profile (MYMOP) (patient-reported symptom burden and daily life impact).
- Study-specific patient satisfaction questions (recommendation, QoL improvement, bowel function improvement, satisfaction, social life changes, and perceived treatment effectiveness).

The primary endpoint was updated prior to final analysis to reflect feasibility outcomes (treatment adherence and therapy switch), given the pragmatic design and emerging relevance of adherence in TAI interventions. These endpoints were assessed at baseline and every 3 months for 12 months to determine the effectiveness and feasibility of TAI compared with best supportive care.

Patients randomized to the intervention group were trained to perform TAI independently, with all the recommendations and instructions provided by the patient representative who was using TAI. The procedure was performed daily and involved the insertion of a cone-shaped catheter into the anal canal. After positioning the catheter, warm water starting with 500 ml was administered into the bowel, typically using gravity. After water administration, the catheter was removed, allowing the bowel contents to evacuate naturally. The patient was contacted within 1 week for any possible issues. If patients tolerated the volume of water, it was gradually increased to 750 and then 1000 ml. If the patient did not tolerate the volume of the water, it was decreased gradually.

The control group received the best supportive care by the treatment protocols established at each participating centre. These protocols included dietary guidelines modifications (patients were advised to chew food thoroughly, eat small, frequent meals, keep a food journal, drink plenty of fluids, and avoid caffeine and alcohol. Recommended foods were as follows: soluble fibre-rich foods—oatmeal, rice bran, barley, apples; stool-thickening foods—bananas, apple sauce, cheese, peanut butter, potatoes, white pasta, pretzels, white rice, white bread, yoghurt, marshmallows, and tapioca; and a lactose-free diet. Some foods to be avoided were gas-producing foods—cabbage, spinach, broccoli, cauliflower, brussels sprouts, radishes, carbonated beverages, onions, beans, corn, cucumbers, nuts, beer, and dairy products; and high-fibre foods (initially)—whole grains and green leafy vegetables. Patients were advised on the administration of bulking agents, the use of loperamide as needed (two tablets (2 mg each; total 4 mg) after first bowel opening, followed by one (2 mg) after every other opening—not exceeding eight tablets (16 mg) per day), and the use of absorbent incontinence underwear. It should be noted that no patients in the control group received interventions, such as sacral nerve stimulation or percutaneous tibial nerve stimulation. None of

the patients were proposed to switch between the groups during the study period—feasibility of the intervention in terms of treatment adherence and switching of therapy was assessed.

Bowel function and QoL were evaluated using the LARS score[21], the Wexner Score[22], MSKCC BFI score[19], and the MYMOP[23] at baseline and every 3 months for a total of 12 months. Six additional questions were asked of patients in the intervention arm during the study. The patients were interviewed by the PI at the relevant centre (the majority of patients were from Lithuania and assessed by the PI Audrius Dulskas). For Lithuanian patients, a standard translation–retranslation procedure was performed. Other patients were fluent in English and filled out the English version of the questionnaires.

The MYMOP tool is a patient-centred, problem-specific instrument designed to capture a patient's perspective on the most important symptoms they experience and the impact these symptoms have on their daily lives[23]. Patients rate the two most significant symptoms associated with their condition and the activities of daily living that are affected by these symptoms. Each is rated by the patient on a scale of 0 to 6, where 0 is 'as good as it can be' and 6 is 'as bad as it can be'. In addition, general well-being can be rated on the same scale, although this is optional for analysis. A change of 0.5–1.0 points in the symptom score following an intervention is considered clinically meaningful, whereas changes greater than 1.0 are considered clinically significant. The MYMOP tool offers a personalized evaluation of the outcomes that are of greatest importance to the patient.

Additional study-specific questions about the TAI intervention were included to capture patients' perspectives on treatment outcomes. The six questions were as follows: *Would you recommend the same treatment to others? Did your quality of life improve? Has your bowel function improved? Are you satisfied with your treatment? Has your social life changed?*, and *Do you think the treatment will help?* Answers were rated on a scale of 1 to 5, from 'not at all' to 'definitely yes'.

For every patient, the following data were recorded and analysed: clinical (age, sex, and comorbidities), tumour characteristics (stage, circumferential resection margin (CRM), size, distance from the anal verge, Dworak grade[24], surgical details (chemoradiotherapy use, operation date), anastomosis (distance from the anus, anastomotic leakage)). For the intervention group, procedure time and TAI-associated complications (pain, tenesmus, dizziness) were recorded. The distance of anastomosis from the anus was measured using a finger or endo(recto)scope. The cancer stage was defined according to the pathological tumour, node, metastasis classification system[25].

Statistical analysis

The original primary endpoint, as specified in the trial protocol and registration, was the difference in LARS scores at 12-month follow-up, with QoL measured using the MSKCC-BFI score as a secondary endpoint. Prior to final analysis, the primary endpoint was refined to focus on feasibility outcomes (treatment adherence and therapy switching), reflecting the pragmatic design of the study and the emerging importance of adherence in TAI interventions. LARS and QoL outcomes were therefore analysed as exploratory efficacy endpoints.

The sample size for the study was determined using G*Power software (Heinrich-Heine-Universität Düsseldorf, Düsseldorf, Germany). With a minimum statistical power of 0.8 to demonstrate a 5-point difference on the LARS scale (with 80% power) between the intervention group and the control group, 34 patients were required to be included (17 in each study arm). Considering a 20% drop-off, at least 20 patients per group were needed. Descriptive statistics were employed to summarize continuous variables, including age, anastomosis distance from the anus, CRM, tumour size, and distance from the anal verge. These variables were presented as median (range). Qualitative variables were presented as absolute frequencies and percentages. Comparisons between groups for continuous variables were conducted using the nonparametric Mann–Whitney *U* test, and the χ^2 test or Fisher's exact test (for small samples) was employed to analyse differences in categorical variables. Significance thresholds were maintained at $P < 0.05$.

Results

Of 250 eligible patients, 162 did not meet the inclusion criteria, of which 158 did not have major LARS, and 47 declined to participate. A total of 41 patients met the inclusion criteria and were randomized to either the intervention group (TAI) or the control group (best supportive care). One patient in the TAI group developed a fistula requiring surgery and was excluded from the study. Data from 40 patients were analysed: 19 patients from the TAI group, and 21 from the control group (*Fig. 1*).

Patient characteristics are summarized in *Table 1*. The median time from primary surgery to study inclusion differed significantly ($P = 0.029$) between the two groups as this was not a stratification criterion during the randomization process. Sex and chemoradiotherapy use distribution did not differ significantly between the TAI and control groups ($P = 0.105$ and $P = 1.000$, respectively). Five patients (25%) from the experimental arm shifted to using enemas every second or every third day or as needed. Ten of the patients (50%) tolerated one 1 l of fluids in the enema, whereas five (25%) had to decrease back to 500 ml.

The median LARS score before TAI treatment was 41 (range 31–42) in the intervention group and 36 (range 31–42) in the control group ($P = 0.137$). At 3 months, the TAI group demonstrated a significant reduction in the LARS score (median 4 (range 0–39)) compared with the control group (36 (22–42)) ($P < 0.001$), showing early improvement in bowel function. This improvement persisted at 6 months, where the TAI group maintained a median score of 3 (range 0–39), whereas the control group remained at 36 (2–42) ($P < 0.001$). By 12 months, the trend continued, with the TAI group showing sustained benefits (median 3 (range 0–39)), whereas the control group experienced no meaningful change (36 (2–42)) ($P < 0.001$) (*Fig. 2*, *Table 2*).

There was no statistical significance in the Wexner incontinence scores between the intervention group (median 17 (range 3–20)) and the control group (14 (4–20)) at the start of the trial ($P = 0.114$). Wexner incontinence scores were also lower in the TAI group after 3 months (median 0 (range 0–15)) compared with the control group (14 (4–20)) ($P < 0.001$). Replicated at 6 months, the scores were TAI group (median 0 (range 0–15)) and control group (14 (4–20)) ($P < 0.001$). At 12 months follow-up, the Wexner incontinence scores in the TAI group stayed the same (median 0 (range 0–15)) and decreased by one point in the control group (13 (4–20)) ($P < 0.001$) (*Fig. 2*, *Table 2*).

At the start of the trial, there was no statistically significant difference between MSKCC BFI scores in the interventional group (mean(standard deviation (s.d.)) 38.21(4.78)) and in the control group (37.67(6.23)) ($P = 0.76$). At 3 months, the median MSKCC BFI score in the TAI group was 89 (range 37–90), substantially higher than the control group's median score of 39 (29–50) ($P < 0.001$). This significant difference persisted at 6 months, with the TAI group maintaining a median score of 89

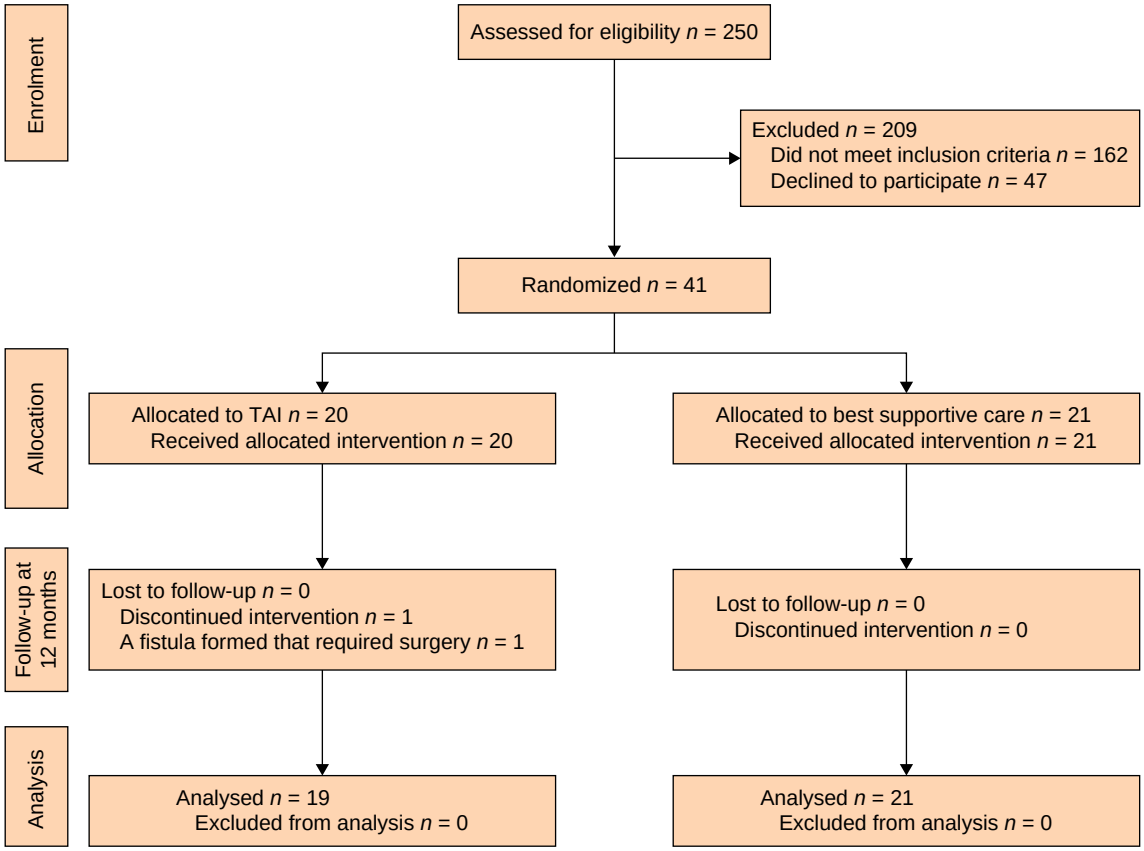

Fig. 1 CONSORT flow diagram for the trial

TAI, transanal irrigation.

Table 1 Patient characteristics of 40 included patients divided into intervention group (TAI) and control group

	Intervention (TAI) (*n* = 19)	Control (*n* = 21)	P*
Age (years), mean(s.d.)	59(10)	63(11)	0.249
Sex			0.105
Male	15 (79%)	11 (52%)	
Female	4 (21%)	10 (48%)	
Smoking	2.0 (10.5%)	3.0 (14.3%)	0.726
Pathology T category ≥ 3	13 (68%)	12 (57%)	0.462
Pathology N category ≥ 1	12 (63%)	8 (38%)	0.113
Tumour level (cm), mean(s.d.)	6.0(2.9)	6.1(3.7)	0.943
Neoadjuvant chemo/radiotherapy use	15 (79%)	16 (76%)	1.000
Stoma rate	15.0 (79.0%)	16.0 (76.2%)	0.839
Time from surgery to stoma closure (months), mean(s.d.)	4.13(1.06)	4.25(1.00)	0.755
Time from stoma closure to inclusion (months), mean(s.d.)	47.86(44.16)	27.25(31.16)	0.148
Time from primary surgery to inclusion (months), mean(s.d.)	66(56)	32(27)	0.029
Height of anastomosis (from dentate line) (cm), mean(s.d.)	3.4(1.0)	3.8(1.0)	0.265
Anastomotic leakage	1 (5)	0 (0)	0.475

Values are *n* (%) unless otherwise stated. TAI, transanal irrigation; s.d., standard deviation; T category, extent of primary tumour; N category, lymph node stage.
* For independent samples t test was used, and Fisher exact test.

(range 37–90) compared with the control group's score of 39 (29–60) ($P < 0.0001$). At 12 months, the TAI group continued to have a median MSKCC BFI score of 89 (range 37–90), whereas the control group demonstrated no change, with a median score of 39 (28–61) ($P < 0.001$).

The MYMOP score of the two most significant symptoms associated with LARS were added together. Before the TAI treatment, the MYMOP scores between the intervention group (median 11 (range 8–12)) and the control group (11 (7–12)) had no statistical significance ($P = 0.1881$). After 3 months, the MYMOP scores were significantly lower in the intervention group compared with the control group, with a median score of 2 (range 0–11) in the TAI group *versus* a median score of 11 (7–12) in the control group ($P < 0.001$).

The TAI procedure time for the intervention group was mean(s.d.) 34.5(13.0) minutes. Two intervention group patients (11%) experienced TAI-associated complications throughout the trial. One patient (5%) experienced tenesmus and another (5%) felt dizziness after TAI.

The results of the study-specific questions indicate a positive patient perspective on the TAI intervention, with all mean(s.d.) scores exceeding 4 (of 5). Patients reported significant

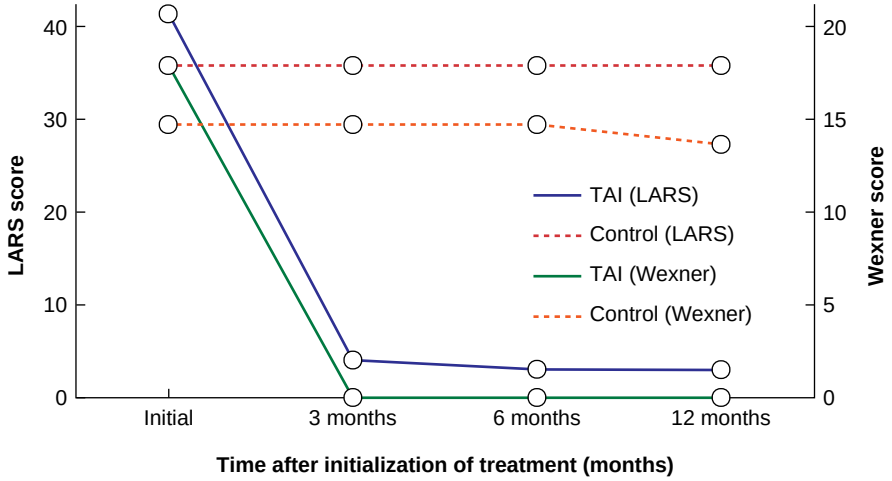

Fig. 2 Line chart comparing median low anterior resection syndrome and Wexner incontinence scores between the intervention group (TAI) and the control group

TAI, transanal irrigation.

Table 2 Comparison of median scores at different time points between intervention group (TAI) and control group in LARS score, Wexner score, and MSKCC BFI score

		0 months		3 months		6 months		12 months	
Outcome measure	**Group**	**Median**	**P***	**Median**	**P***	**Median**	**P***	**Median**	**P***
LARS score	TAI	41	0.137	4	0.001	3	0.001	3	0.001
	Control	36		36		36		36	
Wexner score	TAI	17	0.114	0	0.001	0	0.001	0	0.001
	Control	14		14		14		13	
MSKCC BFI score, mean	TAI	38.21	0.76	89	0.001	89	0.001	89	0.001
	Control	37.67		39		39		39	

Values are median unless otherwise stated. TAI, transanal irrigation; LARS, low anterior resection syndrome; MSKCC BFI, Memorial Sloan Kettering Cancer Center Bowel Function Instrument. *Mann–Whitney *U* test.

improvements in bowel function (mean(s.d.) 4.47(0.96)), QoL (4.42(1.02)), and satisfaction with the treatment (4.21(1.18)). The highest mean(s.d.) score (4.68(0.95)) reflects significant positive changes in social life. Optimism about the treatment's long-term benefits (mean(s.d.) 4.26(0.99)) further emphasized its perceived value, with a majority also willing to recommend it to others (4.05(0.97)). These findings support TAI as a beneficial treatment option from the patients' perspective.

Discussion

This multicentre randomized clinical study of 41 patients has demonstrated that TAI is an effective intervention for improving bowel function and QoL in patients experiencing LARS after rectal resection. At the 12-month follow-up, patients in the intervention group reported improvement in both LARS and Wexner incontinence scores compared with the control group. At 12 months, only 1 of 19 (5.26%) patients in the intervention group continued to experience 'major LARS' whereas 20 of 21 (95.24%) maintained 'major LARS' in the control group. Patients in the TAI group also showed better QoL outcomes, as evidenced by significant improvements in the MSKCC BFI and MYMOP scores. Furthermore, the intervention-specific questions show high satisfaction rates, enhanced social life, and optimism regarding the long-term benefits of TAI. This emphasizes that TAI not only addresses physical symptoms but also positively impacts emotional and social well-being.

Previous studies[13,26–29] have shown that TAI can be beneficial in the treatment of LARS, improving continence and patients' QoL. However, the number of published studies is limited, and they have some limitations. Some studies[13] have included patients with chronic LARS as well as patients with early symptoms after rectal surgery. This may reduce results accuracy, because some patients' symptoms may improve over time after the surgery, whereas others experience colonic dysfunction and nerve damage, which are key factors in LARS symptoms that appear unaffected by time[30]. In other studies[14,16], although patients treated by TAI showed significantly better results, a significant number of patients decided to stop the treatment and relied on supportive therapy only. None of these studies have assessed the feasibility of compliance with the treatment.

Only four randomized clinical trials (RCTs)[14–17] have been published that compare TAI treatment with conservative treatment. The first RCT[17] showed that patients receiving TAI reported significantly better LARS and Wexner scores than the control group at 3- and 6-month follow-ups. However, this RCT[14] assessed the viability of prophylactic TAI, which started directly after stoma reversal, and at 12-month follow-up the LARS score failed to reach a level of significance. In another RCT[16], at 12-month follow-up patients reported significantly lower LARS (22.9 *versus* 32.4; $P = 0.002$) and Wexner scores (6.4 *versus* 9.2; $P = 0.050$) compared with the control group. Intervention group patients also showed improved QoL (8 of 16

EORTC QLQ-C30 QoL-aspects) compared with the control group[16]. The latest study also found that TAI significantly reduced LARS scores compared with standard of care (21.3 *versus* 32.2, $P = 0.008$) and decreased bowel management time, toilet visits, and an improved coping behaviour subscale on the FIQL scale ($P = 0.047$). However, the follow-up period was short (3 months), preventing assessment of long-term efficacy and patient adherence to the treatment.

This study has several strengths. It had an international multicentre design including four European centres. This reduces bias, ensures robust data, and increases the generalizability of the results to different populations and healthcare systems. The extended follow-up of 12 months provides insight into the long-term efficacy and sustainability of TAI. The study included a detailed assessment of QoL using the MSKCC BFI[19], a validated questionnaire specifically designed to assess bowel function following sphincter-preserving surgery for rectal cancer. The study included the feasibility and compliance with the treatment assessment as one of the endpoints. This allows a comprehensive evaluation of patient-reported outcomes beyond bowel function alone. Furthermore, it included the use of a systematic approach to water volume adjustment, starting with 500 ml and gradually increasing to 750 ml and 1 l based on patient tolerance. Included patients had at least 1 year follow-up after surgery. Finally, the study had a low dropout rate and high adherence to the procedure, demonstrating strong participant retention and increasing the reliability of the results. TAI showed a low risk of serious complications.

Despite the promising results, the study has several limitations. First, although the sample size was sufficient to detect statistically significant differences (80% confidence intervals), it was relatively small (40), which may limit the generalizability of the results to broader patient populations and detection of rare adverse effects and subgroup analysis. In addition, the duration of the intervention required significant patient commitment, and compliance was not extensively analysed in this study. Another limitation is the potential for bias in patient-reported outcomes, as patients aware of their allocation to the intervention group may have reported improvements more favourably. Moreover, the heterogeneity of the groups prevents the strong conclusions of the study.

Future research should explore the long-term benefits of TAI beyond the 12-month period while analysing patient adherence to the treatment. Whereas the present study only included patients with severely impaired bowel function, further studies could explore the potential role of TAI as a treatment for patients with minor LARS who do not respond to first-line therapies. Additionally, personalizing TAI protocols based on patient characteristics, such as anastomotic height or baseline bowel function, different TAI usage regimes, and volumes, could further improve their effectiveness.

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Author contributions

Ignas Civilka (CRediT contribution not specified), Michail Klimovskij (Data curation, Resources, Visualization), Andrej Aleinikov (Investigation, Validation, Writing—review & editing), Peter Christensen (Methodology, Writing—review & editing), Narimantas E. Samalavicius (Investigation, Writing—review & editing), Miglė Sakalauskaitė (Data curation, Funding acquisition, Visualization), and Audrius Dulskas (CRediT contribution not specified)

Disclosure

The authors declare no conflict of interest.

Supplementary material

Supplementary material is available at *BJS Open* online.

Data availability

The data that support the findings of this study are available from the corresponding author upon reasonable request

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