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REVIEW

Consensus-driven protocol for transanal irrigation in patients with low anterior resection syndrome and functional constipation

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Abstract

Background This study aims to establish a consensus-based standard protocol for transanal irrigation (TAI) in patients with low anterior resection syndrome (LARS) and functional constipation.

Methods The Delphi method was utilized to reach a consensus among clinicians and nurses expert in the field of colorectal surgery and gastroenterology. To address various uncertainties concerning technical aspects, difficulties, and prescription of TAI, two questionnaires were developed and analyzed in two rounds. A binary approach was employed, setting a consensus threshold of 75% agreement.

Results In the first round, nurses achieved consensus on all statements, while clinicians required a second round to reach consensus, particularly regarding prescription and technical aspects. Clinicians reached consensus on prescribing TAI as a second-line treatment for LARS and functional constipation, following the failure of conservative measures such as dietary and lifestyle interventions. Timing considerations for patients with LARS encompass avoiding TAI within 1 month of stoma closure and waiting a minimum of 3 months. For functional constipation, TAI is recommended for slow transit constipation, emphasizing its preference over surgical options. Consensus was also reached on the choice of catheter for patients with LARS, training requirements for patients and caregivers, preparation of the patient's intestine before TAI, and recommended irrigations.

Conclusions This consensus study successfully developed a standardized TAI protocol for LARS and functional constipation. It provides comprehensive guidelines for prescription and technical aspects, addressing the challenges encountered by healthcare professionals. The protocol aims to enhance patient care, improve treatment outcomes, and contribute to the advancement of TAI.

Keywords TAI · LARS · Consensus-based protocol · Peristeen Plus

Introduction

Transanal irrigation (TAI), also known as retrograde irrigation, is a procedure that facilitates defecation by introducing water through the anus into the rectum and colon [1]. Several studies have shown that TAI is an effective treatment for fecal incontinence and constipation of various causes, low anterior resection syndrome (LARS) and neurogenic bowel dysfunction, and improves disease-related symptoms and quality of life [2–7].

Incontinence and constipation are each estimated to affect around 15% of the adult population [6]. TAI is also suggested to help manage these intestinal conditions, especially when conservative and/or pharmacological approaches—such as dietary changes, oral laxatives, anti-constipation agents, and biofeedback therapy—fail to relieve symptoms [2, 6, 8]. Emptying the left colon and rectum at a specific time prevents leakage of stool between flushes, restoring

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control over the timing and creating a state of pseudo-continence, while regular emptying of the rectosigmoid prevents constipation and reduces the risk of fecal impaction [4, 5].

LARS is a clinical condition that occurs in up to 90% of patients who have undergone a low anterior resection (LAR) of the rectum to remove rectal adenocarcinoma while preserving the sphincter muscle [9, 10]. Symptoms may encompass both fecal urgency or incontinence and voiding difficulty or constipation, significantly impacting the quality of life for patients [3, 9, 10]. Given the effectiveness of TAI in managing fecal incontinence, constipation [2, 5, 6], and neurologic bowel dysfunction [4], multiple studies have been conducted to explore the efficacy of TAI in patients with LARS, consistently demonstrating its positive impact on both the management of symptoms and the improvement of patients' quality of life [3, 7, 11–13]. According to the review by Christensen and Krogh, TAI has achieved an efficacy rate of 79% to 100% in patients with LARS or incontinence after pouch surgery [5].

TAI is not only effective but also safe, easy to learn, can be self-administered, is well accepted by patients, and has been shown to be cost-effective compared to standard bowel care [5, 14–16].

In a recent observational study, the "Sharing Experiences in Coloproctology" group, a team of specialists—some of whom also participated in the development of this consensus—with extensive experience in prescribing TAI and monitoring patients treated with TAI, demonstrated the positive effect of the treatment in the short term—6 months—in patients with functional bowel dysfunction and LARS [7].

Despite its positive outcomes, there is a lack of a unified protocol for prescribing TAI in patients affected by these conditions and there is also a need for shared technical guidelines related to patient training and the management of any challenges that may arise during TAI use. In this study, the "Sharing Experiences in Coloproctology" group proposed to act as a steering committee for a larger study involving other experts from different Italian institutions to conduct a nationwide Delphi study with the aim of reaching consensus and formulating a standard protocol for TAI in patients with LARS and functional constipation.

The expert panel has experience with the use of Peristeen® Plus (Coloplast, Humlebaek, Denmark) [17] as a transanal irrigation system that provides efficient irrigation that can be performed independently by the patient.

Materials and methods

Objective

The aim of this study was to develop a standard protocol for TAI in patients with LARS and functional constipation by assessing the degree of consensus on the topics of interest among healthcare professionals—specialized in colorectal surgery and gastroenterology—from several centers in Italy. The Delphi method was used for this purpose (Fig. 1).

Delphi methodology

The initial phase involved the identification of a pressing issue, recognized by the "Sharing Experiences in Coloproctology" group as the absence of a standardized protocol for TAI treatment in patients with LARS and functional constipation. To establish a unified procedure, a panel of experts in colorectal surgery and gastroenterology, comprising clinicians and nurses, convened for a meeting to share insights based on their expertise and experiences. During this session, ambiguous aspects within the TAI protocol surfaced, leading to the categorization of these issues into corresponding statements. Subsequently, two questionnaires were formulated, one tailored for clinicians and another for nurses.

In the first round of the Delphi method, participants received the questionnaires via email, responding in a binary format (yes/no). A predetermined consensus threshold was established, requiring 75% agreement to reach consensus. During the second round, participants convened for a collective session to deliberate on their initial responses. Following this meeting, a supplementary questionnaire was distributed, featuring solely those items that failed to secure consensus in the preceding survey. The binary approach was again employed, with consensus attained at a 75% agreement threshold.

The flowchart illustrating the Delphi method process is presented in Fig. 1. All procedures were coordinated under the guidance of a facilitator.

Results

The panel consisted of expert colorectal and gastroenterology clinicians and nurses, all of whom completed and returned the first round questionnaires. The questionnaire for clinicians contained 27 statements and the questionnaire for nurses contained 12 statements.

The initial round of the Delphi method achieved consensus among all statements for the nurses' group, whereas the clinicians reached consensus only on 12 select statements. As a result, a subsequent round was specifically undertaken for the clinicians. During this subsequent round, an additional questionnaire was administered, focusing on the statements that did not meet the consensus threshold in the initial round.

The questionnaires covered various aspects of the TAI procedure, including prescribing and technical issues. A dedicated section was meticulously crafted to elicit

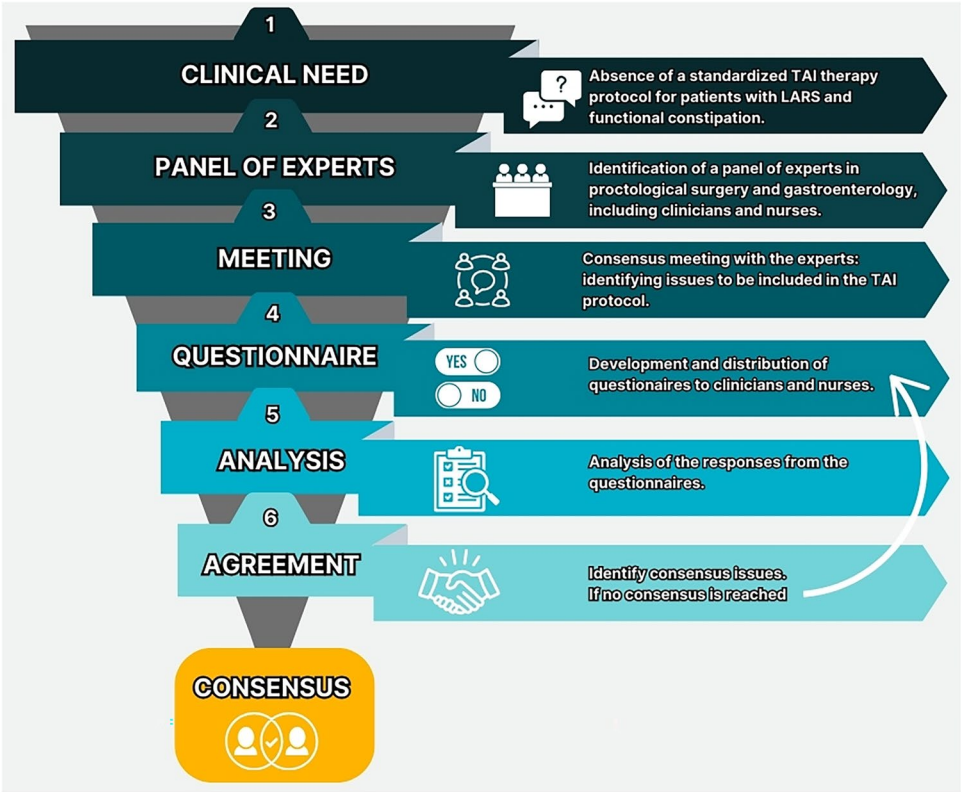

Fig. 1 Flowchart illustrating the stepwise Delphi methodology employed to reach consensus on transanal irrigation (TAI) in patients with low anterior resection syndrome (LARS) and chronic constipation

information regarding challenges or concerns most commonly faced during the TAI process.

Prescription aspects

The prescription issues involved only the clinicians of the expert panel (Fig. 2). During the initial meeting, clinicians outlined their prescription practices, primarily recommending transanal irrigation for patients presenting with functional constipation, fecal incontinence, and LARS. Given the expertise of the clinicians participating in the panel, there was not a consensus of "yes" for the indication of TAI in other conditions such as neurological conditions or injury, as these do not fall within their specific areas of expertise.[1]

The clinicians agreed not to prescribe TAI for individuals who have rectal or colon cancer, acute inflammatory bowel disease, acute diverticulitis, or who have undergone colorectal resection in the last 3 months (with the exception of selected cases where anastomotic integrity was verified). In addition, the physicians recommended excluding patients who had undergone endoscopic polypectomy in the last 4 weeks, those suffering from ischemic colitis, and children under 3 years of age.

The clinicians agreed to exercise caution when using TAI in the following cases: pregnant or breastfeeding women, patients with anorectal conditions that may lead to pain or bleeding (e.g., anal fissures, anal fistulas, or third- or fourth-degree hemorrhoids); patients with anorectal diseases; patients with fecal impaction or severe constipation; patients with diverticulosis due to diverticulitis and/or diverticular abscesses; patients with previous anal or abdominal surgery, long-term therapy with corticosteroids, rectal dressings, anal and rectal stenosis, hemorrhagic diathesis, anticoagulant or antiplatelet therapy (with the exception of aspirin or clopidogrel); patients who have changes in stool form, such as sudden diarrhea of unknown severity and cause, or patients who have undergone radiation therapy in the abdominal or pelvic area.

In this debate, the experts also agreed that the optimal volume of water for irrigation is about 500 ml, consistent with the earlier study by the "Sharing Experience in Coloproctology" group [7].

Regarding LARS, clinicians reached a consensus on the prescription of TAI, depending on specific conditions. TAI should not be prescribed as a prophylactic measure in patients who have undergone low rectal resection and anastomosis within 5–6 cm of the anal verge, nor as a

[1] TAI is effectively employed for neurogenic bowel dysfunctions resulting from neurological injury or conditions such as spinal cord injury, multiple sclerosis, and spina bifida as reported in previous publications [2, 4]. However, our focus was on functional constipation and LARS, as the expert panel lacked expertise in TAI for neurological disorders.

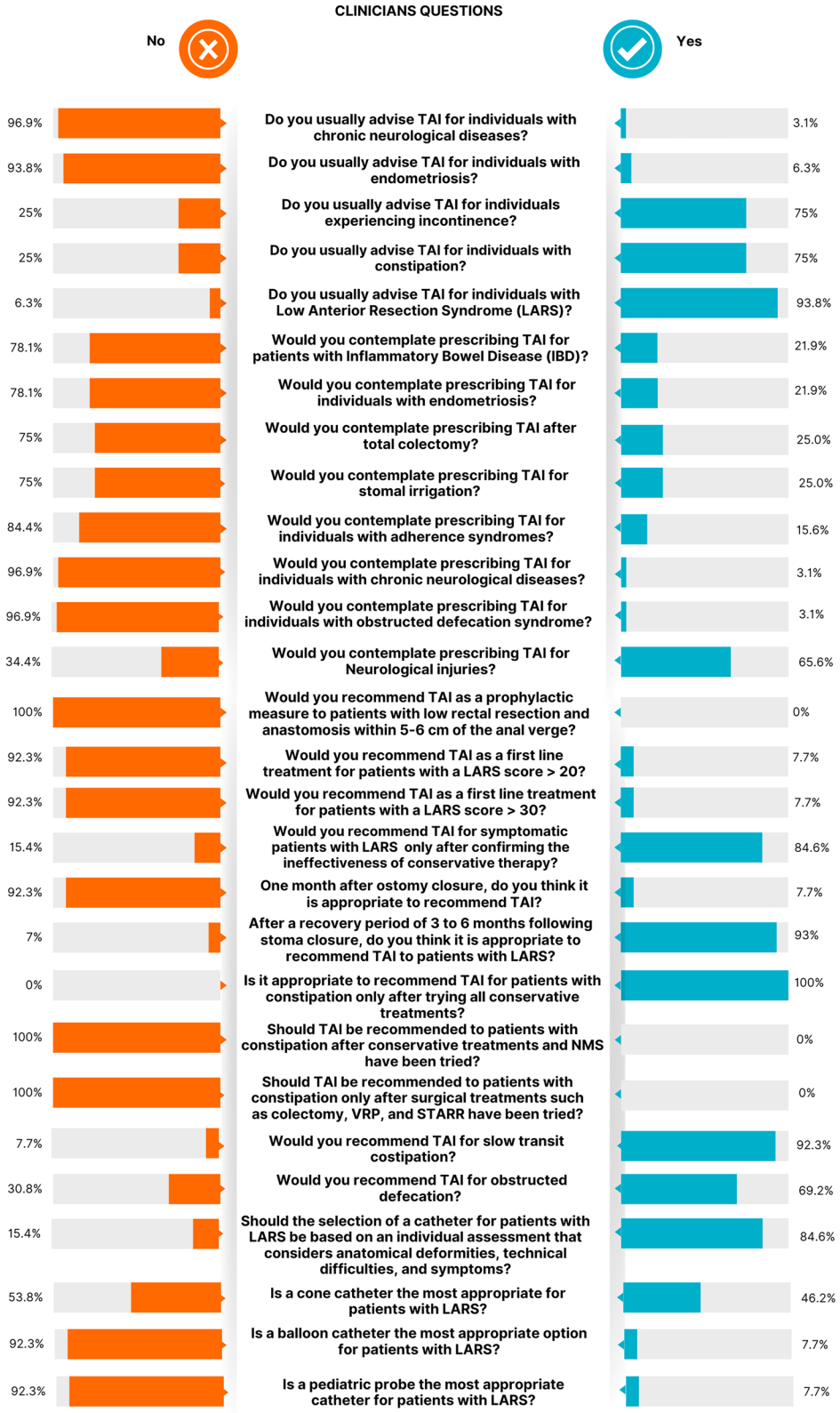

Fig. 2 Expert panel survey questions and responses: the comprehensive list of questions presented to the expert medical panel during the consensus process, detailing the percentage of responses (yes vs. no) for each statement

first-line treatment for patients with mild or severe LARS conditions (LARS score > 20 and > 30, respectively). In contrast, TAI should be recommended to symptomatic patients with mild or severe LARS when conservative treatments such as dietary changes, increased fiber intake, sphincter exercises, voiding scheduling, toilet training, and

low-volume enemas have not proven effective. A consensus was also reached regarding the optimal timing for prescribing TAI to patients with LARS: TAI should not be prescribed within 1 month of stoma closure, but should be considered after a recovery period of 3–6 months.

With regard to functional constipation, clinicians achieved a consensus in prescribing TAI for slow transit constipation. However, there was no unanimous agreement on obstructed defecation, and though the consensus threshold of nearly 75% was almost reached, the concordance rate remained at 69%. The experts uniformly endorsed TAI usage after exhausting all conservative treatments, including rehabilitation. Moreover, the consensus leaned towards TAI as a preferable option over sacral nerve modulation (SNM) and surgical procedures such as colectomy, stapled transanal rectal resection (STARR), and ventral rectopexy (VRP).

Technical aspects

The nurses who were invited to participate in the technical consultation reached a consensus on all the statements in the questionnaire (Fig. 3). They agreed that specific training is necessary to acquire knowledge and skills related to TAI so that they can teach others effectively.

The nurses agreed on the type of training required, recognizing that purely theoretical training is not sufficient: they advocated for a comprehensive approach involving a combination of theoretical and practical components. According to their perspective, the training should include various tools such as information leaflets and live demonstrations of device usage.

Regarding patient education, the nurses agreed that bowel preparation should be recommended prior to TAI training. They emphasized the preference for patients to perform TAI on the toilet rather than in bed and suggested adhering to a

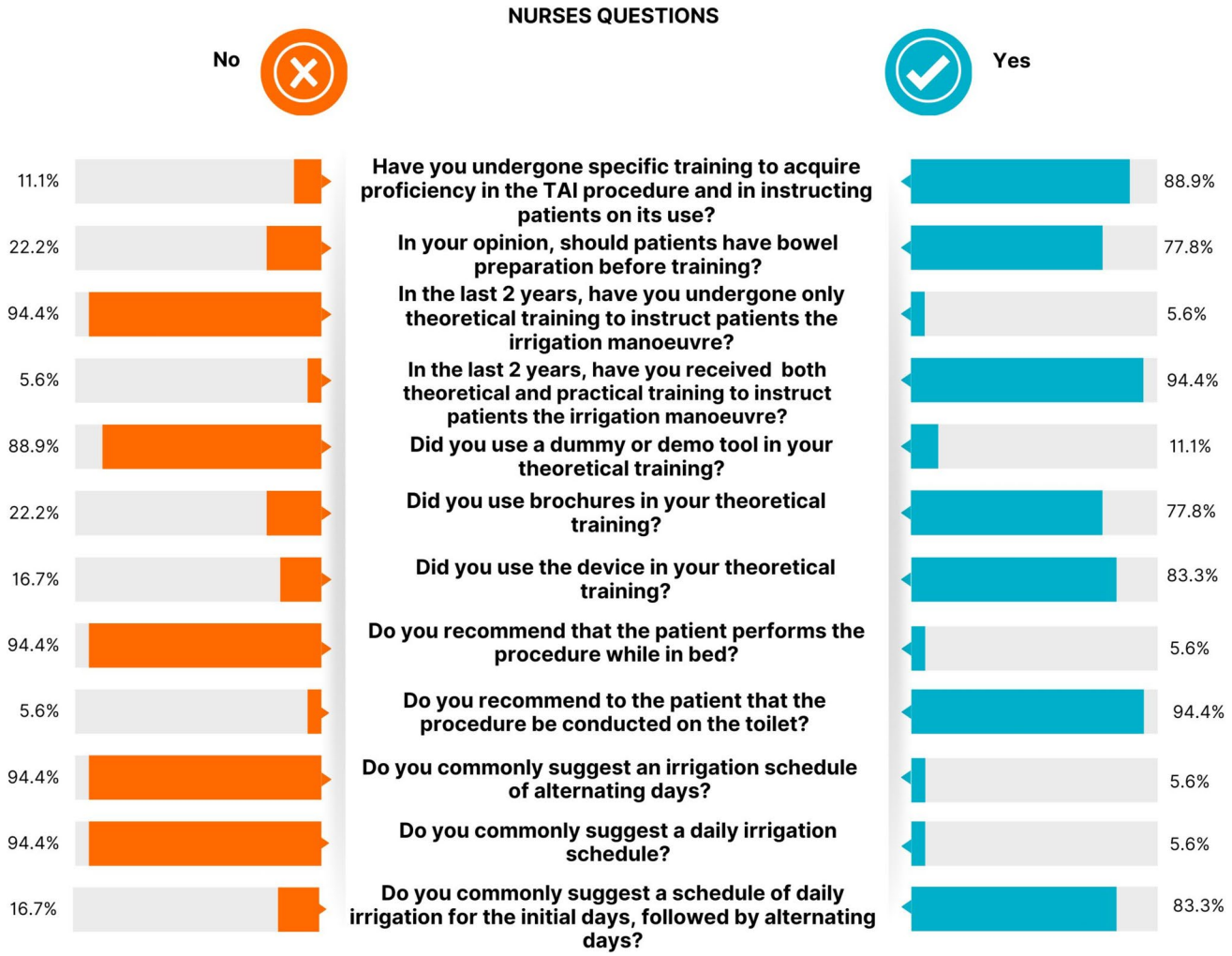

Fig. 3 Expert panel survey questions and responses: the comprehensive list of questions presented to the expert nurse panel during the consensus process, detailing the percentage of responses (yes vs. no) for each statement

specific irrigation schedule. As per their recommendations, an optimal procedure includes a daily irrigation for the initial days, followed by alternate days.

Regarding the technical aspects for clinicians, they were asked about the choice of catheter for patients with LARS. As a result of the variety of catheter types, including conical and balloon, with the latter available in standard or small sizes, it was concluded that a catheter for patients with LARS cannot be selected in advance. Instead, the choice should be made on a case-by-case basis, taking into account anatomical deformities, technical difficulties, and the possible occurrence of symptoms.

Challenges

To gain insight into the challenges encountered by clinicians and nurses in performing TAI, a questionnaire section was devised to collect data on the associated issues. Notably, the results revealed that experts encountered difficulties sporadically, as shown in Fig. 4. However, among the few

Fig. 4 Expert panel survey questions and responses on challenges encountered during TAI procedure: Above, the comprehensive list of questions presented to clinicians is shown, while below are the questions presented to nurses, detailing the percentage of responses (yes vs. no) for each statement

challenges described, clinicians cited difficulty performing sequential steps, introducing the catheter, administering the required amount of water, and understanding device usage. On the other hand, nurses reported, in a few cases, difficulties in communicating with patients, lack of patient trust, and variability in TAI outcomes.

At the conclusion of the consensus process, a practical guide was developed, offering insights into managing common challenges. For each problem identified, Fig. 5 highlights the key issues that clinicians and nurses should consider.

Discussion

Transanal irrigation (TAI) procedure was first described in 1989 when 10 patients with defecation problems following anterior resection used a self-irrigation method and noted a disappearance of frequent urge to defecate [18]. Since then, several studies have demonstrated the efficacy and safety of TAI for a variety of conditions, including functional constipation and incontinence, LARS, and neurogenic bowel disease, ultimately improving patients' quality of life [2, 3, 5–7, 11, 13–15].

Despite TAI being a known practice for a while, the field is still relatively nascent, with a lack of uniform protocols or common guidelines for addressing technical and practical issues. The objective of this article is to provide proctology and gastroenterology professionals with a standardized protocol for TAI in patients affected by LARS and/or functional constipation. Developed through consensus using the Delphi method, the protocol aims to offer comprehensive and lucid guidance on both prescribing and technical aspects of TAI for individuals undergoing this procedure. The prescribing aspects include specific guidelines for patient selection and exclusion, along with precautions for specific patient groups.

In the context of LARS, clinicians have reached consensus on the conditions and timing for prescribing TAI (Fig. 6). It is recommended that TAI should be prescribed as a second-line treatment for symptomatic patients with mild and severe LARS only after more conservative treatments have failed. While a multicenter randomized clinical trial established the superior efficacy of TAI over conservative treatments in enhancing LARS scores for patients [19], it is noteworthy that clinicians still perceive TAI as a somewhat invasive procedure [1]. As a result, they are inclined to recommend it for individuals with more severe bowel conditions, and only after conservative treatments have proven ineffective, as affirmed by a systematic review conducted by Mekhael et al. [2]. In an article by the Harji group, 5% of patients with LARS were found to be refractory to medical treatment 3 months after total mesorectal excision, increasing to 18% at 6 months [20]. This data underscores the importance of considering TAI as a viable option for patients who do not adequately respond to conservative treatments, ensuring they have access to effective management alternatives. Additionally, it is crucial to emphasize that this perceived invasiveness does not equate to a higher risk compared to the potential risks associated with the abuse of laxative drugs [21, 22].

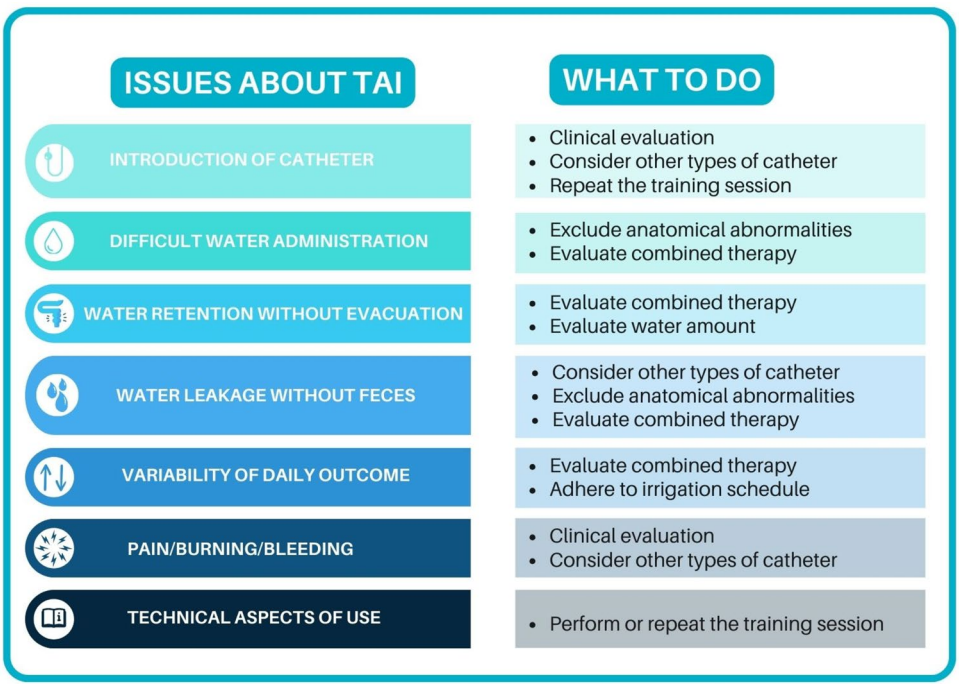

Fig. 5 Key challenges identified in the treatment of patients with transanal irrigation (TAI) and practical recommendations provided by physicians and nurses for managing/resolving these difficulties

Fig. 6 Schematic representation summarizing the take-home messages about TAI prescription and some TAI technical tips for effective management of low anterior resection syndrome (LARS) and functional constipation, as established through expert consensus

The appropriate timing for TAI following lower rectal resection and closure of a stoma is an issue that requires further discussion as it is not clearly established in the literature. Nonetheless, a consensus emerged on this matter: the consensus group agreed that it is advisable not to advocate for TAI within the initial month following stoma closure. While some reports suggest the prophylactic use of TAI within 1 month of protective ileostomy closure [13, 23], the consensus prioritizes patient recovery during this period, recommending a waiting period of at least 3–6 months post-stoma closure. This duration allows the patient adequate time for recovery and functional restoration following the recanalization procedure. Furthermore, it is essential to follow the safety guidelines outlined in the device's instructions for use and to thoroughly assess the patient's condition. A recent randomized trial comparing TAI with conservative treatments included patients 3 months after stoma closure [19]. In the study rectal status was assessed and the anastomosis evaluated before patients were enrolled, emphasizing the importance of the patient's condition in determining the appropriate time to start treatment.

In the context of functional constipation, clinicians agreed to prescribe TAI for constipation with slow transit. Although there was not complete agreement for obstructive defecation, the concordance rate was substantial (69%). It is important to distinguish between the two conditions: performing a digital rectal examination before initiating TAI and confirming the absence of fecal obstruction to ensure the feasibility of TAI.

Parallel to the approach recommended for LARS, the expert panel suggested that TAI should be used as a second-line treatment for functional constipation when all conservative options have been exhausted without success. According to Chaichanavichkij et al. [24], approximately 13.3% of patients with constipation are refractory to conservative treatment. This statistic emphasizes the need for effective alternatives for those patients who do not respond adequately to initial management strategies. Despite being a somewhat invasive procedure, the clinicians concurred that TAI represents a preferable option compared to sacral nerve modulation (SNM) and surgical interventions. This preference is justified by TAI's reversibility and lower risk of adverse events. The majority of symptoms associated with

TAI are reported as mild and transient, with the most serious complication being bowel perforation, which, as reported by Christensen et al., carries an estimated risk of less than 2 per million procedures [1, 5, 14].

Highlighting the significance of patient education is crucial, particularly considering that 67% of perforations occur within the initial 8 weeks of treatment [14]. The data imply a pivotal role for nurses in this context. According to questionnaire responses, nurses acknowledged the importance of comprehensive training encompassing both theoretical and practical aspects, including device usage and simulated explanations, before providing patient instructions. This approach enables nurses to acquire the requisite skills, enabling them to effectively impart the procedure to patients, empowering them to perform it independently and accurately. Therefore, as already reported in the literature, comprehensive patient education is essential for the safe and effective long-term use of TAI [1].

It is important to highlight that nurses observed challenges in patients understanding the procedures and grasping the risk–benefit ratio. This aspect should not be overlooked, especially considering the consensus report by experts [1], which asserts that the treatment's success may be influenced by the patient's psychological state and motivation. This underscores the significance of considering these factors during training.

Regarding the technical aspects, the nurses agreed on several issues related to TAI. According to their recommendations, patients should undergo bowel preparation before training, and TAI should be performed while the patient is on the toilet. Since bowel preparation is the same as that used for a colonoscopy, physicians recommend it only for constipated patients. They also agreed on a specific irrigation schedule, with daily irrigations for the first few days, followed by alternate days.

Adhering to a specific method and frequency of performing the procedure can improve the performance of TAI and address the ineffectiveness and variability of results that healthcare professionals have reported in some cases. Indeed, variations in irrigation program outcomes may be attributed to differences in adherence to the prescribed schedule. Some patients tend to modify the schedule to accommodate daily commitments, thus hindering the consistent achievement of the desired result.

The expert panel agrees on combining TAI with additional treatments, such as the administration of laxatives. In instances where ineffectiveness is attributed to intestinal water retention without subsequent evacuation or water loss unaccompanied by fecal discharge, adjunctive polyethylene glycol (PEG) laxative therapy can be recommended, while it is advisable to avoid cathartic laxatives.

Additionally, as noted by experts, challenges may arise during the procedure, particularly concerning catheter insertion and the precise administration of water. Effectively addressing these challenges requires thoughtful consideration of possible modifications in catheter type and, where necessary, adjustments to the patient's position. Despite the established consensus favoring performing TAI on the toilet, patients should be encouraged to alter their position if difficulties arise, such as attempting insertion in the Sims position.

Nevertheless, in all these scenarios, it may be helpful to reassess the patient from a clinical perspective to identify any potential anatomical abnormalities, such as the development of a rectocele. This reassessment may also be necessary in cases involving pain, burning, and/or bleeding.

To ensure that the patient performs the procedure correctly and adheres to the recommendations, the implementation of a patient monitoring system is recommended. In this context, it may be suggested that a visit or remote monitoring (e.g., by telephone) be carried out after 15 days, followed by a further visit in 4–6 weeks.

In summary, the consensus method has effectively brought together expert opinions to establish a standardized protocol for individuals experiencing LARS and/or functional constipation. The findings offer valuable insights into both prescriptive and technical dimensions, shedding light on the challenges encountered by healthcare professionals during TAI procedures. The standardized protocol, a product of this study, holds potential to enhance patient care and contribute to improved outcomes in the treatment of these conditions.

Author contributions M.J. and F.E. wrote the main manuscript text and prepared figures. The other authors read, revised and approved the final manuscript.

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Data availability No datasets were generated or analysed during the current study.

Declarations

Conflict of interest The authors declare no competing interests.

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