



Transverse perineal support improves long-term outcomes in patients undergoing stapled transanal rectal resection for obstructed defecation syndrome: a multicenter observational case-control study

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Purpose: To evaluate the safety and long-term efficacy of stapled transanal rectal resection (STARR) combined with the transverse perineal support (TPS) procedure in the surgical treatment of obstructed defecation syndrome (ODS) associated with internal rectal prolapse and excessive perineal descent (PD).

Methods: This multicenter observational case-control study involved 7 European centers. During the initial study period, patients underwent STARR alone (group 1), while in the subsequent period, patients received STARR combined with TPS (group 2). All patients were followed clinically at 6, 12, 36, and 60 months, and were offered radiological evaluation between 3 and 5 years postoperatively.

Results: The median postoperative ODS score was similar between groups at 6 months (6 [range, 2–15] vs. 5 [range, 2–13]; $P=0.16$, Mann-Whitney U-test), but at 36 months, it was significantly lower in group 2 compared to group 1 (11 [range, 5–16] vs. 5 [range, 2–15]; $P<0.001$, Mann-Whitney U-test), with stable results maintained through 5 years. The success rate followed a similar trend. Postoperative maximum PD during straining remained unchanged in group 1, whereas it significantly decreased compared to preoperative values in group 2.

Conclusion: The addition of TPS to STARR in the surgical treatment of ODS associated with internal rectal prolapse and excessive PD appears to significantly improve long-term success rates and correct descending perineum.

Keywords: Obstructed defecation syndrome; Perineal descent; Rectocele; Rectal prolapse; Transverse perineal support

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INTRODUCTION

Obstructed defecation syndrome (ODS) is a clinical condition with a multifactorial and still debated pathogenesis [1, 2]. It may result from functional disorders, which are amenable to medical and rehabilitative therapy, and/or from anatomical alterations of the rectum (rectal intussusception and rectocele) and urogenital tract (urogenital prolapse), which may require surgical correction [3].

Perineal descent (PD) is also associated with ODS, as excessive and repetitive straining during defecation can weaken pelvic floor muscles and promote PD. This, in turn, increases the effort required for defecation and may further deteriorate pelvic floor function, establishing a vicious cycle [3–8].

PD appears to play a significant role in the pathogenesis of ODS, occurring almost consistently in patients with long-standing symptoms and, unlike associated morphological rectal anomalies, shows a good correlation with symptom severity [9, 10]. Despite this, the surgical procedures currently proposed for the treatment of ODS are almost exclusively aimed at correcting anatomical rectal alterations such as intussusception and/or rectocele, without addressing the coexisting excessive PD.

Approximately 10 years ago, we proposed a novel surgical technique to correct excessive PD, termed “transverse perineal support” (TPS) [11]. The procedure involves placing a preshaped biologic implant at the level of the perineal body, just above the superficial perineal fascia, and securing it with sutures to the periosteum of the ascending branches of the pubic bone. The rationale is to replicate the function of the transverse perineal muscle, which, unlike the levator ani, contracts during defecation and presumably supports the perineal floor by countering the high intra-abdominal pressure generated during straining [12].

In a pilot study, this procedure was performed in ODS patients with excessive PD and prior surgical failure, demonstrating safety and short-term effectiveness in alleviating symptoms and correcting PD [11].

Since then, the TPS procedure—slightly modified from the original version by using a prepackaged, nonabsorbable mesh—has been increasingly combined with other surgical techniques. These include resective procedures such as stapled transanal rectal resection (STARR) and suspensive techniques such as ventral rectopexy or pelvic organ prolapse suspension (POPS), particularly in the treatment of ODS associated with combined pelvic organ prolapse and excessive PD [13, 14]. However, medium- and long-term clinical outcomes of these combined procedures have not yet been reported, and the clinical relevance of PD correction in ODS remains poorly understood.

In light of these considerations, the aim of this study was to

evaluate the safety and long-term efficacy of STARR combined with TPS in the treatment of ODS associated with internal rectal prolapse and excessive PD.

METHODS

Ethics statement

The study protocol and methodology were approved by the Institutional Board of the Italian Unitary Society of Colonproctology (No. 0005/2024). The study involved human participants and was conducted in accordance with ethical and humanitarian principles, in line with the ethical guidelines of the 1975 Declaration of Helsinki. Prior to surgery, all patients provided written informed consent for participation in the study, the surgical procedure, and the collection, processing, storage, and use of their personal data for scientific research purposes. We also ensured strict confidentiality and anonymity during data analysis and result reporting.

Study design

This research was a multicenter observational case-control study evaluating data from a 10-year cohort of consecutive adult patients who underwent surgery for ODS at 7 European centers: Buonconsiglio Fatebenefratelli Hospital (Naples, Italy), A. Cardarelli Hospital (Naples, Italy), Academy of Applied Medical and Social Sciences (Elbląg, Poland), Pelvic Floor Center, AUSL-IRCCS Reggio Emilia (Reggio Emilia, Italy), University of Campania Luigi Vanvitelli (Naples, Italy), Department of Surgery, University of Bari Aldo Moro (Bari, Italy), and Department of General and Emergency Surgery, CTO Hospital, AORN dei Colli (Naples, Italy). The study is reported in accordance with the STROBE (Strengthening the Reporting of Observational Studies in Epidemiology) statement [15].

Patient selection

From January 2010 to December 2019, all patients with ODS refractory to medical therapy—including a high-fiber diet, adequate hydration, general hygienic-behavioral measures, and laxatives—who were scheduled for surgical treatment at any of the included centers were entered into a prospective database and assessed for eligibility.

All patients underwent a comprehensive clinical evaluation, including gynecological examination in women, colonoscopy, anorectal manometry, and conventional defecography (CD) for isolated ODS. In cases of ODS associated with urogynecological symptoms—such as stress urinary incontinence, vaginal or perineal bulging, and dyspareunia—or signs of anterior and/or middle compartment pelvic organ prolapse on physical examination, dy-

dynamic pelvic floor magnetic resonance imaging (dynamic-MRI) was performed. Additionally, all patients were assessed for symptom severity using a validated ODS score (ODS-S) (Table 1), a simple, disease-specific scoring system consisting of 5 items (excessive straining, incomplete rectal evacuation, use of enemas and/or laxatives, vaginal-anal-perineal digitation, abdominal discomfort). Each item is scored from 0 to 4, for a total score ranging from 0 (no symptoms) to 20 (very severe symptoms) [16]. Health-related quality of life was also evaluated using the 36-Item Short Form Health Survey (SF-36) questionnaire [17].

Based on the preoperative work-up and type of surgical procedures performed, patients were included in the study if they met the following criteria: age between 18 and 75 years, ODS-S ≥ 9 , presence of rectoanal intussusception and rectocele confirmed by CD or dynamic-MRI, and pathological fixed PD (≥ 30 mm from the anorectal angle to the perineal plane at rest) and/or dynamic PD (≥ 30 mm descent from resting position). Eligible patients had received either STARR alone or STARR combined with the TPS procedure.

Patients were excluded if they were under 18 or over 75 years old, had ODS-S < 9 , had organic gastrointestinal diseases, exhibited paradoxical puborectalis contraction, had undergone previous surgery for ODS, or had stage II/III genital prolapse and symptomatic cystocele requiring surgical correction for multicompartiment pelvic organ prolapse.

Surgery

All patients received a 200-mL tap water enema a few hours before the procedure. For antibiotic prophylaxis, cefotaxime (1 g) was administered intravenously 1 hour before surgery. Atropine (1 mg) and midazolam (5 mg; Ipnovel, Roche) were administered intravenously as premedication for subarachnoid anesthesia.

As surgical treatment, patients underwent either STARR alone or STARR combined with TPS. The study was divided into 2 periods based on the surgical technique: during the first 5 years (Jan-

uary 2010 to December 2014), patients received STARR alone (group 1), while during the subsequent 5 years (January 2015 to December 2019), patients underwent STARR in combination with TPS (group 2). In group 2, TPS was performed during the same surgical session, immediately following STARR.

STARR procedure

With the patient in the lithotomy position, after gentle anal massage, a dedicated circular anal dilator was introduced and secured to the perianal skin using 4 stitches placed tangentially to the external anal ring. A circular purse-string suture (or multiple short running circular sutures, depending on surgeon preference) was placed on the rectal wall approximately 2 cm above the internal hemorrhoidal line. A completely open high-volume stapler was inserted, ensuring that the head passed beyond the suture line. The suture ends were threaded through the designated holes in the stapler casing. With constant traction on the suture ends, the stapler was closed, fired, and removed. Bleeding from the stapler line was controlled with hemostatic stitches. A gauze pad was placed in the rectum for several hours. Finally, the circular anal dilator was removed.

TPS procedure

After digital identification of the ischial tuberosities, a 2-cm skin incision was made bilaterally (Fig. 1A). Subcutaneous tissue was carefully dissected using an electric scalpel until the periosteal membrane of the ascending branches of the pubic bone was exposed on both sides at the insertion site of the superficial transverse perineal muscle (Fig. 1B). Blunt dissection of the adipose tissue from the superficial perineal fascia was then performed upward to create a tunnel between the 2 pubic branches (Fig. 1C), through which forceps were passed (Fig. 1D).

A dedicated trapezoidal polypropylene mesh (3 $\times$ 12 cm), tapered at its middle third (Fig. 1E), was positioned just above the superficial perineal fascia (Fig. 1F). The mesh was then sutured to

Table 1. Obstructed defecation syndrome score

Symptom	Never	Rarely	Sometimes	Usually	Always
Excessive straining	0	1	2	3	4
Incomplete rectal evacuation	0	1	2	3	4
Use of enemas/laxatives	0	1	2	3	4
Vaginal/perineal digital pressure	0	1	2	3	4
Abdominal discomfort	0	1	2	3	4

The score includes 5 items specifically related to obstructed defecation syndrome. Each item is scored 0 to 4 (0, never; 1, rarely [< 1 time per month]; 2, sometimes [< 1 time per week, ≥ 1 time per month]; 3, usually [< 1 time per day, ≥ 1 time per week]; 4, always [≥ 1 time per day]) for a total score ranging from 0 to 20, with higher scores indicating greater severity. A score of 9 or higher represents the optimal cutoff to distinguish healthy individuals from affected patients and is associated with a significant reduction in quality of life.

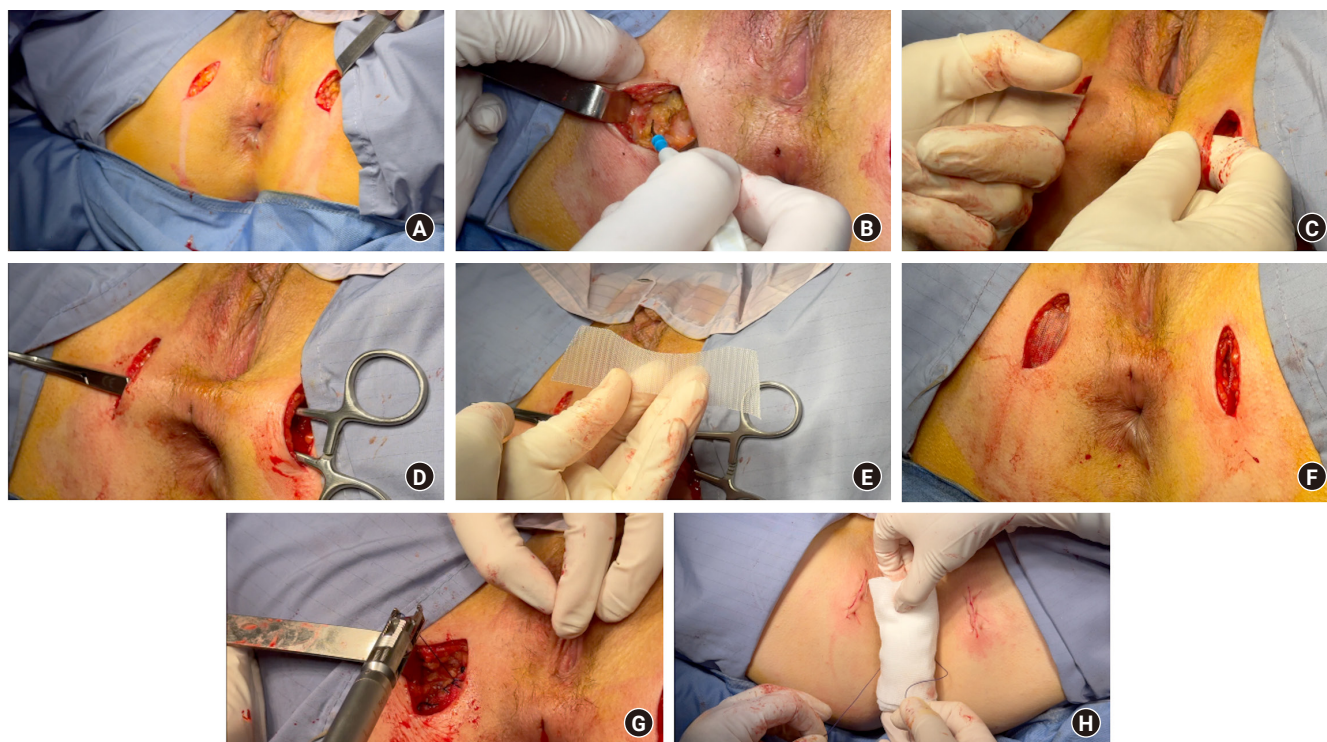


Fig. 1. Surgical steps of the transverse perineal support (TPS) procedure. (A) Identification of the ischial tuberosities and 2-cm skin incisions on each side. (B) Dissection of subcutaneous tissue to expose the periosteal membrane of the ascending branches of the pubis. Blunt dissection of adipose tissue from (C) the superficial perineal fascia and (D) passage of forceps. (E, F) Positioning of a dedicated trapezoid polypropylene mesh. (G) Suturing the mesh bilaterally to the periosteal membrane. (H) Closure of the skin incisions.

the periosteal membrane bilaterally using nonabsorbable suture material (Fig. 1G), and the skin incisions were closed (Fig. 1H).

Follow-up

After discharge, follow-up visits were scheduled at 6, 12, 36, and 60 months after surgery. Follow-up assessments included physical examination, evaluation of ODS-S, and health-related quality of life using the SF-36 questionnaire. At the final follow-up visit, all patients were offered imaging assessment with either CD or dynamic pelvic MRI.

Study outcomes

The primary outcomes of the study were the postoperative median ODS-S and the surgical success rate in the 2 groups at long-term follow-up (5 years postoperatively). In accordance with the results of the ODS-S validation study [16], surgical success was defined as an ODS-S less than 9, while an ODS-S 9 or higher was considered indicative of surgical failure.

Secondary outcomes included patient satisfaction and quality of life, measured using the SF-36, as well as correction of PD as assessed by defecographic or magnetic resonance imaging at a 3-year follow-up.

Regarding the evaluation of descending perineum, the radiological parameter used for data analysis and intergroup comparison was the maximum PD during straining, defined as the perpendicular distance between the anorectal junction and the pubococcygeal line. This parameter was selected based on prior evidence indicating no significant difference in its measurement between patients evaluated in the seated position (used in defecography) and those evaluated in the supine position (used in defecography MRI) [18, 19].

Statistical analysis

Statistical analysis was conducted using Microsoft Excel 2021 (Microsoft Corp). Categorical data were presented as raw numbers with percentages in parentheses. Continuous data were expressed as medians with ranges in parentheses, or as means $\pm$ standard deviations, depending on the data distribution. Differences between groups were assessed using the paired t-test, Wilcoxon matched-pairs signed rank test, Mann-Whitney U-test, or Fisher exact test, as appropriate based on the data distribution. A P-value of less than 0.05 was considered statistically significant.

RESULTS

Study population

During the study period, 382 patients met the inclusion criteria, received surgical treatment, and were considered for enrollment in this study. Of these, 27 patients (7.1%) were lost to follow-up. The remaining 355 patients (32 men and 323 women; median age, 52 years [range, 22–74 years]) completed all scheduled follow-up visits and constituted the final study population.

Among these, 185 patients (52.1%) were treated during the first study period and were included in group 1, while 170 patients (47.9%) received surgery during the second study period and were included in group 2.

Table 2 presents the baseline characteristics of the 2 groups. No statistically significant differences were observed between the groups in terms of median age, sex distribution, ASA physical status, comorbidity prevalence, median ODS-S, or median maximum PD during straining.

Surgery

The mean operative time was 33 ± 3 minutes in group 1 and 50 ± 3 minutes in group 2. Median hospitalization was 2 days (range, 2–5 days) in both groups ($P > 0.99$, Mann-Whitney U-test). No significant intraoperative complications were observed in either group. Urinary retention occurred in 22 patients (6.2%), evenly distributed between the 2 groups (11 in each). During hospitalization (postoperative day 1), 4 patients in group 1 and 3 in group 2 required reoperation due to spontaneous bleeding from the stapled suture line. Additionally, 4 patients in group 1 and 3 in group 2 experienced mild, self-limited bleeding on postoperative day 3. No cases of anastomotic dehiscence or rectovaginal fistula were reported. Temporary fecal urgency occurred in 42 patients (22 in group 1 and 20 in group 2), resolving spontaneously within 6 months in all cases. In group 2, no instances of seroma, mesh detachment, or the need for mesh removal were reported. Moreover, no cases of mesh migration or associated visceral erosion occurred. Approximately one-quarter of group 2 patients (42 of 170) experienced progressive hardening at the implant site, which gradually resolved spontaneously and had completely disappeared in all cases by the 6-month follow-up.

Primary outcomes

The median postoperative ODS-S was similar between the 2 groups at the 6-month follow-up (6 [range, 2–15] vs. 5 [range, 2–13]; $P = 0.16$, Mann-Whitney U-test). However, at the 12-month follow-up, the score was significantly lower in group 2 compared to group 1 (10 [range, 5–16] vs. 5 [range, 2–15];

Table 2. Main baseline characteristics

Characteristic	Group 1 (n = 185)	Group 2 (n = 170)	P-value
Age (yr)	51 (23–74)	52 (22–74)	-
Sex			> 0.99
Female	166 (89.7)	157 (92.4)	
Male	19 (10.3)	13 (7.6)	
ASA physical status			
I	100 (54.0)	91 (53.5)	> 0.99
II	64 (34.6)	59 (34.7)	> 0.99
III	21 (11.4)	20 (11.8)	> 0.99
Comorbidity			
Hypertension	56 (30.3)	52 (30.6)	> 0.99
Diabetes mellitus	30 (16.2)	27 (15.9)	> 0.99
Cardiovascular disease	6 (3.2)	6 (3.5)	> 0.99
COPD	4 (2.2)	3 (1.8)	> 0.99
ODS-S	12 (9–19)	12 (9–19)	> 0.99
Maximum PD (mm)	55 (50–100)	50 (50–80)	0.80

Values are presented as median (range) or number (%). Group 1, patients who received STARR alone. Group 2, patients who received STARR in combination with transverse perineal support procedure.

ASA, American Society of Anesthesiologists; COPD, chronic obstructive pulmonary disease; ODS-S, obstructed defecation syndrome score; PD, perineal descent; STARR, stapled transanal rectal resection.

$P < 0.001$, Mann-Whitney U-test). At 36 months, the median ODS-S was 11 (range, 5–16) in group 1 and 5 (range, 2–15) in group 2 ($P < 0.001$, Mann-Whitney U-test), with stable results maintained through 5 years postoperatively (Fig. 2).

Similarly, surgical success rates were comparable at 6 months (86.5% [160 of 185] vs. 88.2% [150 of 170]; $P = 0.63$, Fisher exact test), but differed significantly at 12 months (43.2% [80 of 185] vs. 87.1% [148 of 170]; $P < 0.001$, Fisher exact test) and remained significantly different at both the 36- and 60-month follow-up points (37.3% [69 of 185] vs. 86.5% [147 of 170]; $P < 0.001$).

Secondary outcomes

Comparison of mean SF-36 scores between preoperative evaluation and the 5-year follow-up showed stable results in group 1 (83.6 ± 4.2 vs. 82.8 ± 4.0 ; $P = 0.08$, paired t-test), but a significant improvement in group 2 (70.3 ± 4.7 vs. 83.2 ± 4.3 ; $P < 0.001$, paired t-test). Among all included patients, 181 (51.0%), 111 from group 1 and 70 from group 2, underwent postoperative radiological reassessment. Comparison of PD in patients who had both preoperative and postoperative imaging revealed that the median maximum PD during straining remained similar in group 1 (55 mm [range, 50–100 mm] vs. 53 mm [range, 50–100 mm]; $P = 0.05$, Wilcoxon matched-pairs signed rank test), whereas it significantly decreased in group 2 (50 mm [range, 50–80 mm] vs. 30 mm

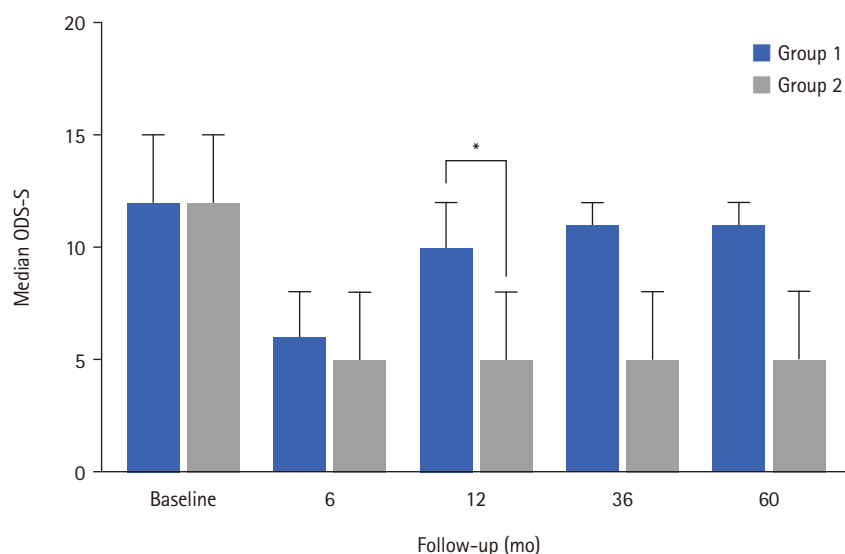


Fig. 2. Median obstructed defecation syndrome score (ODS-S) at each follow-up point in the 2 groups. Group 1, patients who received stapled transanal rectal resection (STARR) alone. Group 2, patients who received STARR in combination with transverse perineal support procedure.

* $P < 0.05$.

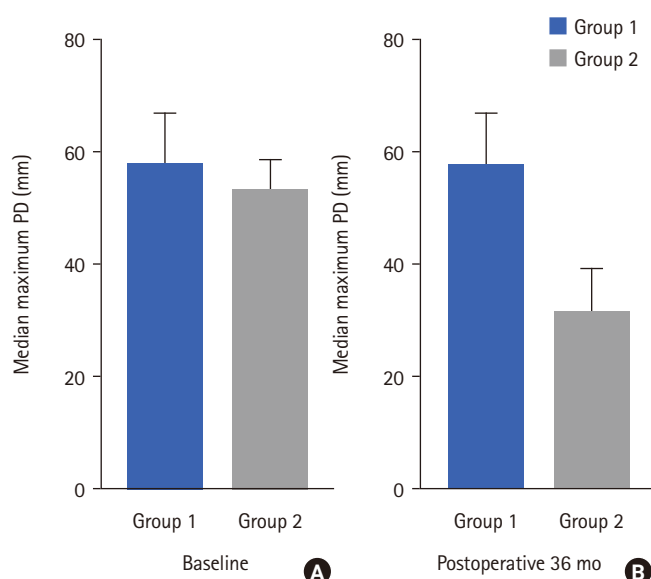


Fig. 3. Median value of maximum perineal descent (PD) during straining in the 2 groups at (A) baseline and (B) the 36-month follow-up evaluation. Group 1, patients who received stapled transanal rectal resection (STARR) alone. Group 2, patients who received STARR in combination with transverse perineal support procedure.

[range, 20–50 mm]; $P < 0.001$, Wilcoxon matched-pairs signed rank test) (Fig. 3).

DISCUSSION

As reported in a seminal manuscript by Parks et al. [7] in 1966, excessive PD may play a significant pathogenic role in ODS. In-

deed, excessive PD is observed in the vast majority of patients with long-standing ODS, particularly when functional defecation disorders are not present [9]. Moreover, unlike morphological rectal anomalies such as rectocele and rectal intussusception, descending perineum is rarely identified in healthy individuals and appears to positively correlate with symptom severity [9, 20, 21].

The association between PD and ODS is rooted in defecatory physiology, particularly in the mechanics of the Valsalva maneuver. In healthy individuals, according to Laplace's law, the maneuver leads to a reduction in abdominal cavity volume and a corresponding increase in pressure, thus facilitating stool evacuation. In individuals with excessive PD, however, the Valsalva maneuver may merely alter the shape of the abdominal cavity, failing to generate the abdominal and pelvic pressure required for effective defecation [11]. Ultimately, excessive PD is associated with a rectal propulsive defect, which may exacerbate obstructive symptoms caused by occult rectal prolapse, such as rectoanal intussusception and rectocele.

Based on previous studies, it is reasonable to hypothesize that the natural history of ODS progresses through 2 distinct phases [12, 22, 23]. The early phase is characterized by stool passage obstruction due to occult rectal prolapse and can be appropriately termed “obstructive.” Over time, continuous and forceful straining during defecation leads to pelvic floor weakening and progressive PD, accompanied by rectal propulsion defects that further aggravate symptoms. In this later phase, which is predominantly characterized by pressure abnormalities resulting from PD, defecation becomes less “obstructive” and more accurately described as “in-

effective.” Consequently, the associated clinical condition might be better defined as “ineffective defecation syndrome” [10].

Despite the well-established relationship between excessive PD and chronic constipation, the majority of current surgical procedures for ODS do not address the rectal propulsive defect secondary to PD. Instead, they primarily aim to correct obstructive morphological abnormalities via internal prolapse resection (e.g., STARR, internal Delorme procedure) or rectal suspension (e.g., ventral rectopexy).

To address the propulsive deficit observed in patients with ineffective defecation, in 2016 we introduced the TPS procedure [11], which mimics the function of the transverse perineal muscle, a structure known to counteract excessive perineal descent. Since its original description, the TPS procedure has been slightly modified by adopting a prepackaged, nonabsorbable mesh, and it has increasingly been performed in combination with other surgical approaches. These include resective procedures, such as STARR, and suspensive procedures, such as ventral rectopexy or POPS, particularly for treating ODS associated with combined pelvic organ prolapse and excessive PD [13, 14, 24].

In this study, we reported the long-term clinical outcomes of this combined surgical approach and specifically assessed the impact of adding the TPS procedure to internal rectal prolapse resection via STARR. Our findings highlight 2 important conclusions. First, the TPS procedure proved effective in the long-term correction of descending perineum. This result not only confirms the findings of our initial pilot study [11] but also lends support to the study by Shafik et al. [12] on the role of the transverse perineal muscle in limiting excessive PD. Second, we observed a notable symptomatic benefit from combining TPS with internal rectal prolapse resection. In patients with ODS and descending perineum, addressing both pathophysiological components—internal rectal prolapse and PD—led to more sustained clinical improvement over time. These findings suggest that in long-standing ODS, optimal outcomes are achieved by targeting both the obstructive (internal rectal prolapse) and propulsive (excessive PD) factors contributing to the syndrome.

In the current study, assessment of the primary outcome (procedural success) was primarily based on a symptom-based score specifically validated for ODS, the ODS-S. In particular, an ODS-S of 9 or higher was considered the optimal cutoff value to distinguish between healthy individuals and actual patients. This threshold was identified in the original validation study as the value offering the best balance between sensitivity and specificity, with a sensitivity of 92% and a specificity of 96% in differentiating healthy participants from ODS patients [16].

Interestingly, the addition of the TPS procedure did not result

in increased hospital stay or complication rates, as no cases of seroma or prosthesis detachment were observed. Although approximately one-quarter of patients undergoing TPS experienced progressive hardening of the implant area, this resolved gradually and spontaneously, disappearing completely in all cases by the 6-month follow-up. This low procedure-related morbidity may represent an additional advantage of combining the STARR and TPS procedures.

Limitations

The main limitations of this study include the strict patient selection criteria, which may have led to the enrollment of a population not fully generalizable to the broader ODS patient population, and the nonrandomized design. In particular, the time-based patient allocation may have introduced selection bias and confounding factors related to temporal trends in patient referral, surgical experience, or adjunctive therapies. Nonetheless, this research could serve as a foundation for the development of a well-designed randomized controlled trial comparing STARR alone versus the combined STARR and TPS approach in treating patients with ODS and excessive PD.

Another limitation is that radiological follow-up was limited to approximately 50% of enrolled patients. However, given the high clinical success rate observed in group 2 at long-term follow-up and supported by the postoperative radiological findings, it is reasonable to extrapolate that the correction of descending perineum demonstrated by defecography or defecography MRI may be generalizable to the broader study cohort.

Conclusions

Based on the results of the current study, the addition of the TPS procedure to STARR in the surgical treatment of patients with ODS associated with internal rectal prolapse and excessive PD appears to result in effective correction of descending perineum and improved long-term success rates, without increasing hospitalization duration or morbidity.

ARTICLE INFORMATION

Conflict of interest

Adolfo Renzi, Luigi Marano, Pasquale Talento, and Antonio Brilantino are editorial board members of this journal, but were not involved in the peer reviewer selection, evaluation, or decision process of this article. No other potential conflict of interest relevant to this article was reported.

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Author contributions

Conceptualization: AR, AB, LM; Data curation: PT, LB, A Pezzolla, DI, CA, MA, A Palumbo, ML, AR, AB, LM; Formal analysis: LD, GM, GC, GT, EMC, AR, AB, LM; Methodology: AR, AB, LM; Supervision: FD, DB, GDS, AR, AB, LM; Validation: FD, DB, GDS, AR, AB, LM; Writing—original draft: all authors; Writing—review & editing: all authors. All authors read and approved the final manuscript.

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