

ORIGINAL ARTICLE



IDEAL Stage 2a/b prospective cohort study of transanal transection and single-stapled anastomosis for rectal cancer

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Abstract

Aim: There are several anastomotic techniques available to facilitate restorative rectal cancer surgery after total mesorectal excision (TME), including double-stapled anastomosis (DST) and handsewn coloanal anastomosis (CAA). However, to date no one technique is superior with regard to anastomotic leakage (AL) or functional outcomes. Transanal transection single-stapled anastomosis (TTSS) aims to overcome some of the technical challenges and offer comparable clinical and functional outcomes to traditional anastomotic techniques. The aim of this study was to explore the role of TTSS in modern rectal cancer surgery and to provide comparative clinical and functional outcome data with DST and CAA.

Method: A prospective cohort study was undertaken to assess the safety and clinical and patient-reported outcomes associated with the TTSS procedure. All patients undergoing sphincter-preserving surgery for rectal cancer with an anastomosis performed within 6 cm of the anal verge between January 2016 and April 2021 were prospectively enrolled into this study. Clinical and patient-reported outcome data, including low anterior resection syndrome (LARS) assessment, were collected. The primary endpoint was anastomotic leakage within 30 days.

Results: A total of 275 patients participated in this study, with 70 (25%) patients undergoing a TTSS, 110 (40%) undergoing a DST and 95 (35%) undergoing a CAA. Patients undergoing a CAA had more distal tumours than those having a TTSS or DST, with a median tumour height of 5, 7 and 9 cm ($p < 0.001$), respectively. We observed a statistically significant reduction in AL in the TTSS group compared with the DST group, with rates of 8.6% versus 20.9% ($p = 0.028$). There was no difference in LARS scores between patients undergoing TTSS and DST ($p = 0.228$), while patients with a CAA had worse LARS scores than TTSS patients ($p = 0.002$).

Conclusion: TTSS is a technically safe and feasible anastomotic technique in rectal cancer surgery as an alternative to DST and CAA. Its advantages over DST are a reduced AL rate and, over CAA, improved function. It should therefore be considered as an alternative technique to improve clinical and patient-reported outcomes in restorative rectal cancer surgery.

KEYWORDS

anastomosis, Rectal cancer, single stapled

INTRODUCTION

There are a variety of available anastomotic techniques to facilitate restorative surgery following total mesorectal excision (TME) for rectal cancer, ranging from stapled to handsewn anastomosis, including the construction of colonic reservoirs. However, there is no good quality evidence demonstrating the superiority of any single technique with regard to the potential sequelae of restorative surgery, including anastomotic leakage and functional impact [1, 2]. The double-stapled anastomosis (DST) technique for colorectal anastomosis is the most widely used worldwide as it is perceived to facilitate the formation of a low colorectal anastomosis relatively easily [3, 4], with acceptable rates of anastomotic leakage of 8.4%–12.3% [5–7]. However, there are several technical drawbacks of DST, which may have a theoretical impact on anastomotic leakage rates. These include the number of linear stapler firings required during rectal division, the formation of lateral intersecting staple lines (dog ears) and the intersections of staples lines after the double-stapling technique. This is compounded by the difficulties encountered with pelvic dissection and formation of intracorporeal colorectal anastomosis in a narrow pelvic cavity with current minimally invasive platforms due to a multitude of anatomical, technical and patient factors.

An alternative to DST is hand-sewn coloanal anastomosis (CAA), which is traditionally reserved for patients with ultralow rectal tumours requesting restorative surgery [8] or in cases of technical difficulties whereby a low colorectal anastomosis is converted to a CAA [9]. CAA is associated with high rates of morbidity, with reported rates of overall morbidity up to 47%, anastomotic leakage rates of 8.5% and an increased risk of long-term bowel dysfunction [10].

To overcome some of the difficulties encountered with laparoscopic DST for mid and low rectal cancer the transanal TME (TaTME) bottom-up approach was developed. The theoretical principles of TaTME of early transanal transection and retrograde dissection facilitate the improved dissection of the distal TME, allow for a controlled distal margin and enable a single-stapled or hand-sewn anastomosis, with reported anastomotic leakage rates of 9.0%–15.7% [11, 12]. However, this technique has not been able to gain traction beyond expert centres due to the associated high risk of intraoperative urethral injury and reports of early multifocal recurrence [13, 14].

More recently, the TaTME procedure has been further refined by Spinelli et al. [15] to develop transanal transection single-stapled anastomosis (TTSS). The TTSS technique builds on the transanal transection and anastomotic components of TaTME, with some technical differences, and combines this with traditional TME dissection. It facilitates a stapled transanal anastomosis and has the potential to mitigate the difficulties encountered with DST and the potential complications and long-term functional sequelae encountered with handsewn anastomosis. TTSS has been carefully developed using the principles from the IDEAL framework, highlighting its key steps within a proof-of-concept study [15]. Early results report a statistically significant reduction in the anastomotic leakage rate for a TTSS group compared with DST and TaTME, with reported rates of 2%, 17.5% and 6% ($p=0.005$), respectively [16].

What does this paper add to the literature?

We have robustly evaluated the transanal transection single-stapled anastomosis (TTSS) technique in keeping with the principles of an IDEAL Stage 2a/b study. TTSS is an emerging and evolving concept in sphincter-preserving surgery and is a potential alternative technique in mid and low rectal cancer.

The recent 'pause' on TaTME surgery in some countries and by some professional organizations [13] due to a multitude of reservations represents a new era in surgical innovation. This 'pause' is due to a series of concerns expressed regarding the TaTME technique, including the incidence of overall morbidity including urethral injury [17], carbon dioxide embolism [18] and anastomotic leakage [13], multiple low-volume surgeons performing TaTME [19] and the associated poor oncological outcomes, with emerging reports of high local recurrence rates with a multifocal pattern of disease [13]. Significant variation has been observed in outcomes differing between high- and low-volume centres and expert surgeons in performing TaTME. Current guidance advocates the use of TaTME to be limited to expert surgeons while high-quality evidence continues to be accrued [20].

The reporting of some of the procedural difficulties encountered with TaTME reflects the transparent nature of modern surgical innovation, focusing on open outcome reporting of negative and positive outcomes, and safe evaluation and adoption of new techniques. It is essential that surgical innovation continues to be robustly evaluated, and that TTSS is evaluated in the same manner. This IDEAL Stage 2b exploratory study aims to explore the application of TTSS in modern rectal cancer surgery further by reporting comparative clinical and functional outcome data with traditional DST and CAA.

METHOD

This study was designed in keeping with the principles of the IDEAL (Idea, Development, Exploration, Assessment and Long-Term Monitoring) framework and maps to Stage 2a and 2b: development and exploration [21]. Institutional ethical approval was obtained for this study. This study has been reported in keeping with the IDEAL reporting guidelines [22].

IDEAL Stage 2a: development

Based on our extensive experience with TaTME we modified the transanal approach to facilitate an anastomosis. Our technique broadly follows the same principles as described by Spinelli et al. [15], but modifying, in patients with very low rectal tumours, the

operative sequence of the transanal approach electing to start with this approach prior to transabdominal TME dissection. In higher rectal tumours we complete the transabdominal TME dissection first followed by the transanal approach.

We outline the steps of our modified TTSS technique.

1. Place a Lone-Star® retractor (CooperSurgical™ Inc, Trumbull, CA, USA) and insert a swab in the rectal lumen proximal to the tumour.
2. Perform a full-thickness circumferential rectotomy 1–2 cm distal to the tumour and above the level of the anorectal junction.
3. Close the rectal lumen with 3/0 vicryl. Lavage with betadine before and after luminal closure.
4. Continue dissection for approximately 1 cm cranially to meet the previous abdominal TME dissection or to enter the TME plane if starting the dissection transanally.
5. Deliver the specimen transanally or transabdominally based on tumour-specific characteristics and deliverability of the specimen through the anal canal.
6. Proximal division of the colon with insertion of the circular anvil. Attach a tube to the circular anvil and reposition the colon into the pelvis.
7. Place a purse string suture using a 3/0 PDS on the distal rectal cuff.
8. Deliver the tube transanally through the middle of the purse string and remove it from the anvil. Connect the stapler to the anvil and tie the distal purse string around the stapler and form the single-stapled anastomosis.
9. Reinforce the staple line circumferentially transanally with an interrupted 3/0 PDS.

All anastomoses were tested intraoperatively with indocyanine green fluorescence imaging to ensure vascular integrity, and a transabdominal air leak test was performed.

IDEAL Stage 2b: prospective cohort study

A prospective cohort study was undertaken to assess the safety, clinical and patient-reported outcomes associated with the TTSS procedure. All patients undergoing sphincter-preserving surgery for rectal cancer between 1 January 2016 and 30 April 2021 in our institution were prospectively enrolled into this study with a comparative assessment between patients undergoing TTSS and DST or CAA. These two groups were to assess differences between patients requiring a low colorectal anastomosis (DST versus TTSS) and a coloanal anastomosis (TTSS versus CAA).

Eligibility criteria

The eligibility criteria for this study included all adult patients (>18 years old) undergoing a TME for rectal cancer with an

anastomosis performed within 6 cm of the anal verge. Patients were excluded if they underwent intersphincteric resection with a CAA or a delayed CAA.

Patient consent

All patients were extensively counselled preoperatively, with written informed consent obtained for all participating patients. Patients undergoing TTSS were informed of the key steps of the technique, the experience of the operative surgeon and the relatively new experience with the technique in our institution. Patients were informed that they would be closely followed-up postoperatively to assess for anastomotic leakage and functional outcomes.

Endpoints

The primary endpoint was anastomotic leakage within 30 days. The International Study Group of Rectal Cancer definition was used for anastomotic leakage, which defines anastomotic leakage as a defect of the intestinal wall at the anastomotic site (including suture and staple lines of neorectal reservoirs) leading to a communication between the intra- and extraluminal compartments [23].

Secondary endpoints included postoperative complications, grade of complications, reoperation rate, length of stay and functional outcome. Postoperative complications were classified as adverse events within 30 days of the operation and were classified according to the Clavien–Dindo (CD) classification [24]. The CD classification consists of the following grades: 0, no complications; I–II, minor complications; III–V, major complications. The highest ranking complication was recorded for each patient. Reoperation rates were reported as any unplanned reoperation within 30 days of the index operation. Length of hospital stay was defined as the number of days following the day of surgery until medically fit for discharge.

Postoperative functional outcomes were assessed using the low anterior resection syndrome (LARS) score, a well-validated scoring system consisting of five questions that was developed specifically for use in patients undergoing restorative rectal cancer surgery [25]. The score ranges from 0–42 points and stratifies patients into three categories: no (0–20 points), minor (21–29 points) or major (30–42 points) LARS.

Key outcomes related to surgical innovation were reported in keeping with the COHESIVE core outcome set (COS) to assess and measure the seamless, standardized evaluation of innovative surgical procedures and devices [26]. The COS consists of six innovation-specific domains: modifications, unexpected disadvantages, device problems, technical procedure success, whether the overall desired effect was achieved, and surgeons'/operators' experience. Two domains relate to intended benefits and expected disadvantages.

Statistical analysis

Categorical and dichotomous variables are expressed as number and percentage. Continuous variables are expressed as mean and standard deviation or as median and interquartile range. A chi-square test was used to compare categorical variables and nonparametric tests were used to compare continuous variables. All tests were two-sided, with type I error set at $\alpha=0.05$. All analyses were conducted using IBM SPSS Statistics version 26.0.0.1 for Macintosh (IBM Corp., Armonk, New York, USA).

RESULTS

Between 2016 and 2021, a total of 275 consecutive patients participated in this study, with 70 (25.4%) patients undergoing a TTSS, 110 (40.0%) undergoing a DST and 95 (35.1%) undergoing a CAA. Patients undergoing a CAA had more distal tumours than those with a TTSS and DST, with a median tumour height of 5, 7 and 9 cm from the anal verge to the lower border of the tumour ($p<0.001$), respectively (Table 1). A higher proportion of patients in the TTSS and CAA groups underwent neoadjuvant treatment compared the DST group, with overall rates of 73%, 72% and 52% ($p=0.003$), respectively. Patient- and tumour-related characteristics are outlined in Table 1.

Operative decision-making

The decision to perform a DST, TTSS or CAA was at the discretion of the individual operating surgeon and on whether the patient required a low colorectal anastomosis (DST or TTSS) or a coloanal anastomosis (TTSS or CAA). Patients with mid rectal cancer (5–10 cm from the anal verge) underwent either DST, TTSS or CAA while patients with low rectal cancer (0–5 cm from the anal verge) underwent either a TTSS or a CAA. All patients had an anastomosis performed within 6 cm of the anal verge; the height of the anastomosis was lower in patients with a CAA compared with TTSS and DST ($p<0.001$). A statistically significantly greater proportion of patients with a CAA had a defunctioning ileostomy compared with TTSS, with respective rates of 93% and 77% ($p=0.005$). Patients with a TTSS were statistically significantly more likely to undergo early closure of ileostomy ($p=0.033$) compared with those having a CAA. Table 2 highlights the relevant surgical details.

Postoperative outcomes

We observed a statistically significant reduction in anastomotic leakage in the TTSS group compared with the DST group, with rates of 8.6% versus 20.9% ($p=0.028$) (Figure 1, Table 3). However, when comparing TTSS with CAA there were no statistically

TABLE 1 Patient and tumour characteristics.

Variable	TTSS (n=70)	DST (n=110)	CAA (n=95)	p	p (TTSS vs. DST)	p (TTSS vs. CAA)
Male sex	43 (61)	73 (66)	69 (73)	0.306	0.500	0.128
Age (years) ^a	64 (36–87)	65 (30–86)	66 (23–84)	0.369	0.768	0.217
Tumour height (cm) ^a	7 (3–12)	9 (6–13)	5 (2.5–12)	<0.001	<0.001	<0.001
Tumour location						
Low rectum (0–5 cm)	14 (20)	0 (0)	50 (53)	<0.001	<0.001	<0.001
Mid rectum (5–10 cm)	56 (80)	110 (100)	45 (47)			
Tumour size (cm) ^a	5 (1–14)	5 (1–12)	4.5 (1.5–15)	0.362	0.697	0.213
Radiological tumour stage						
T1–2	11 (16)	18 (16)	22 (23)	0.358	0.908	0.237
T3–4	59 (84)	92 (84)	73 (77)			
Radiological nodal stage						
N0	15 (21)	28 (26)	22 (23)	0.901	0.727	0.709
N1/2	52 (74)	79 (72)	71 (75)			
Nx	3 (4)	3 (3)	2 (2)			
Radiological metastasis	13 (19)	11 (10)	8 (8)	0.105	0.090	0.105
Neoadjuvant treatment	51 (73)	57 (52)	68 (72)	0.003	0.005	0.856
CT and CRT ^b	9 (13)	7 (6)	19 (20)			
Chemoradiation	38 (54)	42 (38)	44 (46)			
Chemotherapy	4 (6)	8 (7)	5 (5)			

Abbreviations: CAA, coloanal anastomosis; DST, double-stapled anastomosis; TTSS, transanal transection single-stapled anastomosis.

^aMedian (range) as defined from anal verge to lower border of the tumour.

^bInduction chemotherapy (CT) and chemoradiation (CRT).

TABLE 2 Surgical details.

Variable	TTSS (n = 70)	DST (n = 110)	CAA (n = 95)	p	p (TTSS vs. DST)	p (TTSS vs. CAA)
Surgical approach						
Open	3 (4)	8 (7)	2 (2)	<0.001	0.018	0.388
Laparoscopic	54 (77)	62 (56)	81 (85)			
Robotic	13 (19)	40 (36)	12 (13)			
Height of anastomosis (cm) ^a	3.75 (2–5)	5 (3–6)	3 (1–5)	<0.001	<0.001	0.001
Defunctioning ileostomy	54 (77)	79 (72)	88 (93)	0.001	0.428	0.005
Early closure of stoma	9/54 (17)	14/79 (18)	5/88 (6)	0.039	0.874	0.033
Colonic pouch	9 (13)	9 (8)	12 (13)	0.495	0.308	0.966

Abbreviations: CAA, coloanal anastomosis; DST, double-stapled anastomosis; TTSS, transanal transection single-stapled anastomosis.

^aMedian (range) as defined from the anal verge to the anastomosis.

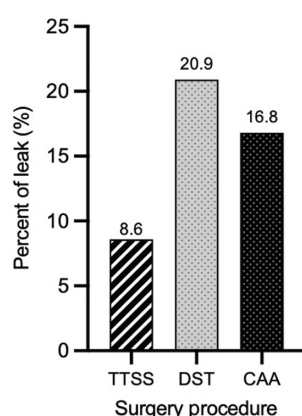


FIGURE 1 Anastomotic leakage according to surgery (TTSS, transanal transection single-stapled anastomosis; DST, double-stapled anastomosis; CAA, coloanal anastomosis).

significant differences observed in anastomotic leakage rates (8.6% vs. 16.8%, $p=0.122$). There were no statistically significant differences observed between DST and TTSS or between TTSS and CAA with regard to length of stay, morbidity and overall margin status.

Functional outcomes

There were no statistically significant differences in functional outcomes between TTSS and DST ($p=0.228$), whereas patients undergoing CAA had a worse LARS score than TTSS patients ($p=0.002$) (Figure 2, Table 3).

Surgical innovation outcomes

There were no modifications to the technique during the IDEAL Stage 2b study. Technical success was achieved in all 70 (100%) TTSS procedures with the overall desired effect of achieving an intraoperative, transanal, single-stapled anastomosis. No

technique-related intraoperative problems were encountered. Expected disadvantages of anastomotic leakage were observed in 6 (8.6%) patients, with no unexpected disadvantages encountered. TTSS was an easy to use and logical procedure for the operating surgeons.

DISCUSSION

TTSS is an emerging and evolving concept in sphincter-preserving surgery and is a potential alternative technique in mid and low rectal cancer. In our IDEAL Stage 2a/b study we demonstrate its utility in facilitating sphincter-preserving surgery and demonstrate its advantages over DST with regard to reduced anastomotic leak rates ($p=0.02$) and preserving postoperative function when compared with CAA ($p=0.001$). Furthermore, we confirmed the safety of the TTSS technique with no adverse impact on clinical outcomes, including postoperative morbidity, or oncological outcomes compared with DST or CAA.

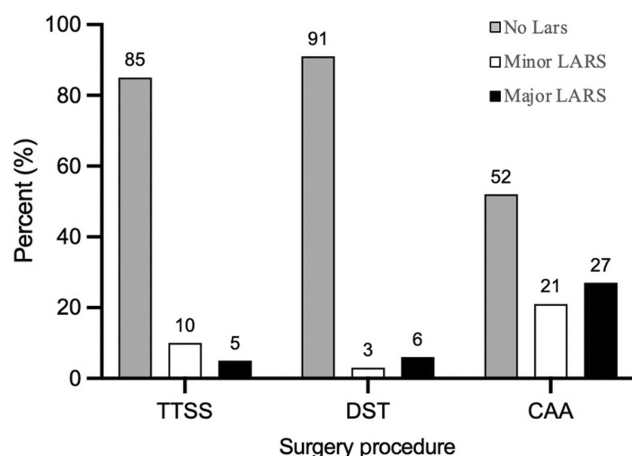
Our study includes a high-risk patient cohort within the TTSS group compared with the DST group, with a higher proportion of low rectal tumours ($p<0.001$), greater use of neoadjuvant treatment ($p=0.005$) and the formation of a lower anastomosis ($p<0.001$). These clinical factors are well-recognized risk factors for anastomotic leakage; however, despite this, our observed rate of anastomotic leakage was statistically significantly lower in the TTSS group compared with the DST group for mid rectal cancer, with rates of 8.6% and 20.9%, respectively ($p=0.02$). We hypothesize that the observed differences are likely to be due to the technical differences between the two stapling techniques, centred mainly around the use of a single stapler firing coupled with the avoidance of intersecting staple lines. Similarly, we note statistically significant differences between the TTSS and CAA cohorts with low rectal cancer, including the greater proportion of low tumours ($p<0.001$) and the formation of a lower anastomosis with the CAA cohort, with a median anastomotic height of 3.75 cm in the TTSS group compared with 3 cm in the CAA group ($p=0.001$). This observed difference in tumour height and anastomotic height

**TABLE 3** Postoperative clinical and functional outcomes.

Variable	TTSS (n = 70)	DST (n = 110)	CAA (n = 95)	p	p (TTSS vs. DST)	p (TTSS vs. CAA)
Length of stay (days) ^a	6 (3–39)	6 (2–42)	6 (2–55)	0.695	0.792	0.691
Postoperative morbidity						
No morbidity	37 (53)	67 (61)	53 (56)	0.795	0.483	0.932
Clavien–Dindo I–II	31 (22)	26 (24)	28 (30)			
Clavien–Dindo III–V	11 (16)	17 (16)	14 (15)			
Anastomotic leakage	6 (8.6)	23 (20.9)	16 (16.8)	0.092	0.028	0.122
Margin status R1	2 (2.9)	8 (7.3)	6 (6.3)	0.452	0.320	0.469
LARS score at 12 months	(n = 41)	(n = 78)	(n = 52)	<0.001	0.228	0.002
No LARS (<20)	35 (85)	71 (91)	27 (52)			
Minor LARS (21–29)	4 (10)	2 (3)	11 (21)			
Major LARS (30–42)	2 (5)	5 (6)	14 (27)			

Abbreviations: CAA, coloanal anastomosis; DST, double-stapled anastomosis; LARS, low anterior resection syndrome; TTSS, transanal transection single-stapled anastomosis.

^aMedian (range).

**FIGURE 2** Low anterior resection syndrome (LARS) score according to surgery (TTSS, transanal transection single-stapled anastomosis; DST, double-stapled anastomosis; CAA, coloanal anastomosis).

between the two techniques is likely to reflect the need for an appropriate distal oncological margin in lower tumours, which may have precluded the technical ability to perform a TTSS in very low tumours, as an adequate distal cuff is required for stapling. In very low rectal tumours TTSS may not be a feasible option and a handsewn CAA may be more appropriate. We did not observe a statistically significant difference in anastomotic leakage rates between the two cohorts, with an observed rate of 8.6% in the TTSS group versus 16.8% in the CAA group ($p=0.122$). However, this observed reduction in anastomotic leakage rates in high-risk low rectal cancer with the TTSS technique fails to achieve statistical significance and therefore warrants further exploration and investigation. Our work supports the recently published observations by Spinelli et al. [16], that TTSS is associated with lower rates of anastomotic leakage in low rectal cancer.

It is important to understand the functional sequelae of sphincter-preserving surgery when developing new anastomotic techniques. LARS contributes to long-term bowel dysfunction [2, 10] and can have a profound impact on a patient's quality of life [10], and has a reported prevalence rate of 34%–49%. TTSS is an attractive alternative option to CAA, as it combines controlled transanal transection with the formation of a lower anastomosis without detriment to postoperative functional results. Our study reports preserved functional outcomes in the TTSS group, with a lower rate of major LARS compared with CAA (5% vs. 27%, $p=0.002$).

The key strengths of our work are the robust outcome reporting with the use of well-defined and robust definitions for all key clinical and patient-reported outcomes. The use of standardized definitions is essential in ensuring accurate outcome reporting when assessing and evaluating a new surgical technique. We acknowledge the limitations of our work, which include selection bias in the choice of anastomotic technique based on surgeon preference and patient characteristics.

Surgical innovation requires robust evaluation prior to its wider dissemination, and adopting the principles of the IDEAL framework ensures that this is done in a systematic and structured manner. The development of TTSS has clearly followed this path, with Spinelli et al. [15, 16] demonstrating its proof of principle, highlighting technical modifications and publishing early clinical data, thus mapping to 'Stage 1: idea' and 'Stage 2a/b: development and exploration'. Our Stage 2a/b exploratory study contributes to the ongoing development of TTSS by highlighting some simple modifications to the technique and by reporting early clinical and patient-reported outcomes. The ongoing evaluation of TTSS requires a stable intervention to be agreed by expert consensus. Definition of surgical interventions including their constituent parts is essential in ensuring standardized delivery and evaluation, as advocated by the Blencowe framework [27]. Determining the typology and flexibility of the TTSS intervention in keeping with this framework will form part of the key next

steps in its ongoing robust evaluation. Using the Blencowe framework will ensure the 'deconstruction' of the TTSS approach into its component parts, thus ensuring intervention refinement, including identifying appropriate modifications that do not significantly deviate from the overall intended intervention. This approach to intervention standardization facilitates balance and pragmatism regarding intervention fidelity and delivery. Following on from standardizing the TTSS intervention we aim to perform a multicentre prospective cohort study, in line with a true IDEAL Stage 2b study. This will allow us to determine key aspects of methodological design for a future trial, including the generation of sufficient data to help estimate effect size, definition of intervention standards, assessment and acknowledgment of learning curves, exploration of subgroup differences, analysis of adverse events and elicitation of stakeholder preferences. Based on the results of this IDEAL Stage 2b study we will design our IDEAL Stage 3 definitive, randomized controlled trial. This will evaluate the TTSS approach using a standardized and stable intervention within the context of a robust trial design and will provide data on broader outcomes of clinical effectiveness and cost-effectiveness. It will be this stepwise evaluation of TTSS and evidencing of its effectiveness that will lead to its widespread adoption and integration into clinical practice.

AUTHOR CONTRIBUTIONS

Benjamin Fernandez: Data curation. **Lara Boissieras:** Methodology; data curation. **Bertrand Celerier:** Conceptualization; data curation; writing – review and editing. **Eric Rullier:** Conceptualization; methodology; writing – review and editing. **Quentin Denost:** Conceptualization; methodology; writing – review and editing; formal analysis; supervision.

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None to declare.

CONFLICT OF INTEREST STATEMENT

The authors declare no conflicts of interest.

DATA AVAILABILITY STATEMENT

Data sharing is not applicable to this article as no new data were created or analyzed in this study.

ETHICS STATEMENT

Institutional ethical approval was provided for this study.

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