Title: The Current State of the Transanal Approach to the Ileal Pouch-Anal Anastomosis

Short Title: The Current State of TaPouch

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Structured Abstract

Background

The transanal approach to pelvic dissection has gained considerable traction and utilization continues to expand, fueled by the transanal total mesorectal excision (TaTME) for rectal cancer. The same principles and benefits of transanal pelvic dissection may apply to the transanal restorative proctocolectomy with ileal pouch-anal anastomosis (IPAA)- the TaPouch procedure. Our goal was to review the literature to date on the development and current state of the TaPouch.

Material and methods

We performed a PubMed database search for original articles on transanal pelvic dissections, IPAA, and the TaPouch procedure, with a manual search from relevant citations in the reference list. The main outcomes were the technical aspects of the TaPouch, clinical and functional outcomes, and potential advantages, drawbacks, and future direction for the procedure.

Results

The conduct of the procedure has been defined, with the safety and feasibility demonstrated in small series. The reported rates of conversion and anastomotic leakage are low. There are no randomized trials or large-scale comparative studies available for comparative effectiveness compared to the traditional IPAA.

Conclusion

The transanal approach to ileal pouch-anal anastomosis is an exciting adaption of the transanal total mesorectal excision for refining the technical steps of a complex operation. Additional experience is needed for comparative outcomes and defining the ideal training and implementation pathways.

Keywords: Inflammatory Bowel Disease; Ulcerative Colitis; Familial Adenomatous Polyposis; transanal total mesorectal excision; ileal pouch-anal anastomosis; restorative proctocolectomy; transanal proctectomy

Introduction

When surgery is necessary, the restorative proctocolectomy and ileal pouch-anal anastomosis (IPAA) is the procedure of choice for patients with chronic, medically refractory mucosal ulcerative colitis (UC), indeterminate colitis (IC), familial adenomatous polyposis (FAP), and select patients with Crohn's disease (CD). The IPAA offers excellent long-term functional results and quality of life. However, there is a substantial rate of pouch-related complications, which can have a significant impact on functional outcomes and, quality of life, and may ultimately result in pouch failure [1, 2].

Technical advances, such as using minimally invasive surgery (MIS) for the IPAA procedure, could help minimize these risks. MIS has proven benefits, but the application of a MIS approach in Inflammatory Bowel Disease (IBD) has been limited with the existing platforms [3, 4, 5-7]. While laparoscopic IPAA is safe, feasible, and has clinical benefits over open surgery, there are technical limitations with the laparoscopic approach, such as the anatomic constraints of the fixed, bony pelvis, and the challenges of visualization and instrumentation in the deep pelvic dissection [11].

To overcome these limitations with laparoscopy, new MIS methods have been developed, including the minimally invasive transanal approach [8, 9]. The transanal approach was initially described with a total mesorectal excision (TaTME) for rectal cancer resections, and remains the most common indication [10]. However, the advantages of the transanal approach can be applied to other pelvic dissections, such as the IPAA, for better visualization of the distal rectum, a more precise pelvic dissection, and a lower rate of conversion to open surgery [12]. Moreover, the simultaneous two-team approach can facilitate the dissection and shorten the operative time [13]. With these potential benefits, the state of transanal IPAA surgery (TaPouch) warrants further examination. The goal of this work was to review the development and current state of the TaPouch. As the transanal approach could be a useful tool to facilitate the application of minimally invasive surgery in this patient population, we felt this review was important.

Material and methods

Clinically relevant areas and applications of the TaPouch were established. The following areas were deemed relevant to investigate: the technical conduct of the operation, the

learning curve and assessment of competency for safe implementation, clinical and functional outcomes, risks and benefits of the TaPouch compared to the traditional abdominal approach to IPAA, and future directions for further study with this new technique.

Within each defined area, the team searched the PubMed database from database inception to June 1, 2018, for original articles about the transanal IPAA. The following search terms were used: "transanal surgery", transanal minimally invasive surgery", "restorative proctocolectomy", "IPAA", and "J pouch", with "colorectal", "surgery", "colorectal surgery", "inflammatory bowel disease", AND "IBD". Reference lists were hand searched, and searches were also done for authors the team recognized as experts in the field. Articles were included if published in English and the full text was available. Conference proceedings and videos were not included. Abstracts were initially independently reviewed by FBL and DSK for relevance to the defined sections and novelty. The full text of the selected articles was reviewed by all authors.

Ethical Statement

Given the project's review design of published material, lack of human subjects, live data, or a study protocol, this project was exempt from Institutional Review Board approval at Columbia University Medical Center and the Hospital Clinic of Barcelona granted exemption from Ethics approval.

Results

Technical Conduct of the Operation

Since the original description of the IPAA by Parks and Nicholls, little evolution has occurred in the technical configuration of the pouch reservoir [21, 22]. The J- pouch is the preferred configuration due to the simplicity of construction, durability, and function. Over time, construction of the anastomosis moved from a hand-sewn to a double-stapled technique –with or without mucosectomy– for reported lower complication rates and better functional outcomes [23].

The operation is performed in stages, per surgeon preference and patient factors, with the IPAA fashioned at the initial total proctocolectomy or, more commonly, at the completion proctectomy. There are two distinct phases for the restorative proctectomy with IPAA-

an abdominal and a transanal phase. The abdominal phase can be performed through an open or MIS approach, including multiport, hand-assisted, and single incision laparoscopic and robotic platforms [14-20]. If using a two-team approach, both teams can work simultaneously, with the abdominal and transanal teams meeting around the level of the peritoneal reflection. The transanal phase starts with a Lonestar retractor (CooperSurgical, Trumbull, CT, USA) to efface the anal canal followed by the introduction of a transanal platform, such as the GelPoint® Path (Applied Medical, Rancho Santa Margarita, CA, USA) or rigid transanal endoscopic microsurgery platform (TEM, Richard Wolf GmbH, Knittlingen, Germany)- to access the rectal lumen. Continuous insufflation helps maintain a stable pneumorectum for improved visibility. A 0-Polypropylene purse-string suture is placed to close the rectal lumen. The amount of mucosa preserved on the rectal cuff is based on the degree of proctitis and presence of dysplasia. Leaving a 1-2 cm of the rectal cuff reduces the risk of incontinence or other detrimental functional outcomes, and is appropriate in mild proctitis or cases with no dysplasia [24]. The purse-string placed about 3 cm proximal to the dentate line is tied down, and the rectotomy is marked circumferentially with the spatula or hook cautery approximately at 1 cm from the knot, where the mucosal folds end.

Mesorectal dissection can be performed as a close rectal dissection (Fig. 1), versus a formal total mesorectal excision (TME) [14, 25, 26]. The rectal specimen may be retrieved through the stoma site or a left iliac fossa incision, if there is no diverting stoma. If there is an ileostomy already in place or planned, the J-pouch may be constructed through the stoma site at the beginning of the procedure, or after the proctectomy has been completed, then returned to the abdomen for the anastomosis (Figs. 2 and 3). To assist in ensuring optimal vascularization of the pouch, intraoperative perfusion assessment using a fluorophore, such as indocyanine green (ICG) may be conducted; the fluorescence angiography can help in deciding which vessels to safely transect without jeopardizing the optimal perfusion of the pouch [20].

With the TaPouch, the anastomosis is usually performed in a double purse-string technique, which has the theoretical advantages of a better assessment of the length and mucosal quality of the rectal cuff, and direct visualization of the ideal level for the distal anastomosis, for a more precise resection [14]. For the stapled pouch anastomosis, a second 0 or 2-0 Polypropylene purse-string suture is run on the distal rectal cuff. Then, a

28mm or wider intraluminal stapler is used to staple the anastomosis. To help guide the spike of the stapler through the purse-string, a silastic drain tube can be inserted on the spike and passed through the purse-string before it is tied down (Fig. 4) [27]. Under direct visualization, the tube attached to the spike is pulled intra-abdominally. The tube is removed, the anvil is attached to the spike, and the stapler is fired. A final assessment of the pouch is performed using a leak test for the integrity of the anastomosis and ICG angiography to ensure adequate mucosal and anastomotic perfusion [20]. Per surgeon preference, a protective loop ileostomy may be created. A drain may be placed either across the anastomosis through the transanal approach or in the pelvis through a port site.

Outcomes of the technique

The literature is evolving with outcomes for this new approach to IPAA. Currently, there are no randomized trials or large cohort studies available. Details of the published series to date are shown in Table 1. Based on the included studies, the rates of conversion and anastomotic leakage range from 0 to 18.7% and from 0 to 6.2%, respectively. In order to safely implement the TaPouch into clinical practice, there is a need for structured and proctored training.

Initial reports describing the feasibility of the TaPouch were performed on animals and cadavers, with successful mesorectal dissection, transanal specimen extraction and no conversions [29, 30]. de Buck et al demonstrated the feasibility in UC patients, performing TaPouch surgery using single stapled anastomosis with multiport or single port laparoscopy in 11 patients [18]. Leo et al. presented the outcomes of 16 UC patients undergoing a hybrid single-incision surgery combined with TaTME for ileoanal pouch construction [17]. The first two patients had a hand-sewn anastomosis, and the subsequent 14 had a stapled anastomosis. The median operative time was 247 (range, 185-470) minutes, and the median hospital stay was 6 (range, 3–20) days. Only one case of anastomotic leakage was reported at two weeks postoperatively. Closure of the loop ileostomy was performed at a median of 6 (range, 5–12) months after surgery.

The first study comparing short-term outcomes of transanal and transabdominal approaches for IPAA described 97 transanal patients and 119 transabdominal patients [14]. Post-operative morbidity, mean operative time (211 vs. 218 minutes), conversion rate (7.4 vs. 23.5%), and length of stay (7.34 vs. 9.08 days) were lower in the TaPouch

group, while anastomotic leakage rate was comparable in the two groups. Only two studies reported long-term complications after TaPouch [25, 35]. Tasende, *et al*. described one (6.25%) case of pouchitis diagnosed five months after surgery, which was successfully treated with antibiotic therapy. Moreover, two (12.5%) patients developed anastomotic stenosis that required dilatation. Ambe, *et al*. described a case of pouch shrinkage six months after its construction, which is believed to have been caused by a significant degree of pouch ischemia. This patient was successfully treated with a re-pouch construction.

Discussion

Advantages of the transanal platform

General advantages of the transanal approach are applicable to the IPAA. There is better visibility compared to the traditional abdominal top-down approach. Clear visualization of the pelvis could help the surgeon avoid inadvertent injury of pelvic structures, and nerves, which impact functional and sexual outcomes after surgery [31, 32]. The bottom-up dissection approach allows access to the pathology from below, avoiding the inflammatory changes, fibrosis, and disrupted planes from prior surgery, which could provide advantages to reaching the dissection field over the abdominal approach [33].

In pouch creation, the transanal platform has been reported to confer the advantage of easier dissection of the distal 5 cm of the rectum before pouch formation [15, 17]. The single stapled or hand-sewn anastomosis created enables the surgeon to examine the quality of the mucosa at the distal anorectum to be used for anastomosis and the level of the anastomosis which is not easily done with double-stapled anastomosis [14]. In a stapled approach, the TaPouch may also avoid multiple stapler firings when resecting the distal rectum, which has been described with the laparoscopic approach and is associated with higher risk of anastomotic leakage [34].

From the authors' clinical experience, stapling from below also permits less retained rectum than a laparoscopic or robotic dissection, which could have important clinical implications for future dysplasia. This important benefit of TaPouch surgery can be demonstrated in patients with FAP, where there is a 100% chance of progression to colorectal cancer, necessitating complete removal of the mucosa. Through the transanal platform, the surgeon can identify the dentate line to ensure a narrow transitional zone is

maintained, minimizing the odds of leaving mucosa behind [35]. Minimizing the cuff may also reduce the incidence of cuff adenomas, which can be encountered after conventional laparoscopic double-stapled ileoanal anastomosis in these patients. Furthermore, the transanal approach for proctectomy facilitates the access to the narrow pelvis and compensates for the lack of triangulation created by single-port surgery [18].

Disadvantages of the transanal platform

The drawbacks of the transanal platform are not specific to the IPAA procedure but related to the differences in pattern recognition, the anatomic planes from approaching the operation from the bottom up, and procedure-specific risks. This different anatomic approach necessitates a long learning curve with structured training and proctoring in order to become familiar with this new anatomic perspective.

Transection of the rectum at the beginning of the procedure may increase the risk of bacterial contamination, with subsequent abscess formation. This was highlighted by Velthuis et al. in rectal cancer patients treated with TaTME, and is applicable to TaPouch, as well [36]. A complication that can be specific to the transanal approach is the injury of the urethra and urethral sphincter in up to 10% of patients [37]. Neurogenic bladder dysfunction and urinary retention are possible sequels of the conventional abdominal TME dissection but can occur after transanal dissection as well [38]. The insufflation of CO_2 to create pneumorectum can distort the planes and may extend the lead to erroneously dissect deeper beyond the correct plane, potentially damaging the autonomic nerves and venous plexus [39]. Functional outcomes of TaPouch surgery with regard bowel, bladder, and sexual function and quality of life continue to evolve. To date, published reports are centered on TAMIS and TaTME for benign and malignant rectal cancer lesions, a population not directly comparable [40, 41]. Further experience and published reports will elucidate the long-term sexual, urinary, and bowel functional outcomes of TaPouch.

Future directions to advance the current technique

Application of new surgical technology and experience with the procedure will help shape the future direction of the TaPouch. The most exciting technology to advance the procedure may be the rollout of the single port robotic systems. As described, the constraints of access using rigid, ‘straight’ laparoscopic instruments through the current transanal platforms require a new skillset. However, the next generation robotic platforms

offer a chance to use ‘wristed’ instruments with superior image resolution through a transanal approach.

The current models offer both a rigid platform and a flexible platform, which can pair trans-stomal or trans-umbilical surgery with the transanal IPAA, which could move towards direct organ target natural orifice transluminal endoscopic surgery (NOTES) applications in the future- where the surgeon accesses the peritoneal cavity via a hollow viscus to perform the procedure [42]. As we look to the future, NOTES optimization for transanal extraction will depend on the gender, size of the specimen, and use of wound protector tools. At the present time, the technologies can advance the concept of “incisionless surgery” as the TaPouch procedure can help in the safe selection of patients who can avoid a protective ileostomy. With the precise transection and single-stapled anastomosis, there is a different risk-benefit ratio for performing covering ileostomies. Instead of diverting with this anastomosis, a Foley catheter or Penrose drain can be placed in the pouch transanally across the anastomosis, avoiding the ileostomy. This represents one less operation for patients, with all associated benefits. More experience with this technique will show the feasibility, safety, and lower expected rates.

Another important application of technology is fluorescence angiography. Intraoperative assessment with fluorescence angiography has shown significant benefit for confirming adequate blood flow to the anastomosis and guiding resections for benign and malignant disease [43-45]. There are specific benefits for fluorescence angiography in pouch construction, where it can be invaluable to demonstrate the vascular map to the visualize accurately which arteries are supplying the ileocolic region of the future pouch and ensuring the appropriate branches are resected and saved for optimal vascularization of the pouch during lengthening procedures [20].

A key point for the future of the TaPouch is proper training and implementation of this technically complex procedure. The best training model to date for new technology has been the TaTME, with pretraining, clinical and cognitive skills training, proctored introduction into clinical practice, and registry assessment of outcomes [10, 46-49]. A similar pathway is recommended for training and implementation of the TaPouch procedure. However, at the current time, widespread training for extensive utilization of the TaPouch is not recommended. As the technical steps and outcomes are evolving, it is

suggested that experienced specialists should apply the technique in centralized, high-volume centers for refinement and the best potential outcomes. Continued evolution of the procedure will come from experience and published outcomes in controlled studies.

Conclusions

The transanal approach offers a new option for minimally invasive pouch surgery, aimed to improve some challenging technical steps of a complex operation. Its main features (good visualization in the **low pelvis**, controlled **transection** of the height of the rectum, single stapled **anastomosis**) overcome some limitations of traditional minimally invasive techniques. The application and literature continue to grow with the feasibility and outcomes of the TaPouch and the preliminary results are encouraging, but data on its long-term outcomes have to be generated and scrutinized. Further experience in specialized centers will help in evaluating the placement of this approach in the armamentarium of colorectal and IBD surgeons.

Table and Figure Legend:

Table 1: Summary of Published TaPouch Series in Human, Cadaver, and Animal Models

Figure 1: Transanal proctectomy by close rectal dissection

Figures 2-3: J-pouch constructed through the stoma site

Figure 4: Pouch anal anastomosis using a circular stapler guided by a silastic drain on the spike

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