Transanal Proctocolectomy And Ileal Pouch-Anal Anastomosis (TaIPAA) For Ulcerative Colitis: Medium Term Functional Outcomes In A Single Centre.

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Abstract

**Background:** Transanal dissection of the rectum has been recently introduced for ileal pouch-anal anastomosis (IPAA) in UC showing promising results. Thanks to the precise identification of the rectotomy site the risk of long rectal stump is avoided, and a single stapled anastomosis is performed easily.

The aim of this study is to analyze our initial experience of transanal IPAA (Ta-IPAA), considering postoperative complications and medium-term functional outcomes.

**Methods:** Our Center has experienced the transanal approach for proctectomy and IPAA since October 2018. All patients underwent Enhanced Recovery After Surgery (ERAS) protocol. Postoperative complications occurring within 30 days after surgery were taken into consideration. Fecal continence, genito-urinary activity and global quality of life at 1 and 6 months after ileostomy reversal have been assessed.

**Results:** Until March 2019, 8 patients underwent Ta-IPAA. In all cases the laparoscopic approach was performed during the transabdominal phase; abdominal drainage was never used. At the time of the pouch construction a defunctioning loop ileostomy was created in all patients. Stoma closure was performed in all cases at a median time of 6 months after surgery. Postoperative complications occurred in only one patient, who showed rectal bleeding. There were no cases of anastomotic leakage.

Medium-term functional outcomes were determined prospectively by a validated questionnaire (Cleveland Global Quality of Life). Fecal incontinence for liquid or solid stool, genitourinary and sexual functions were also investigated, showing comparable results with the literature data.

**Conclusions:** In our experience, Ta-IPAA provided good short and medium-term functional results in UC.

Background

Restorative proctocolectomy is widely adopted in the treatment of ulcerative colitis\(^1\),\(^2\),\(^3\) as well as in other inflammatory and neoplastic conditions, requiring an ileal pouch-anal anastomosis (IPAA) to reconstruct gastrointestinal continuity to the anus\(^4\).

Conventionally, either the laparoscopic or the open approach can be employed to gain rectal dissection and creation of ileal pouch-anal anastomosis. Pouch-anal anastomosis is usually made using a stapler, leaving a 2 cm rectal cuff in order to preserve continence and to reduce the risk of inflammatory recurrence or dysplasia\(^5\). The dissection of the last centimeters of the rectum, rectum resection and ileal pouch-anal anastomosis could be demanding from a technical point of view due to narrow pelvic space and cross stapling of the distal part of the rectum is often challenging for surgeons.
Transanal total mesorectal excision (TaTME) has been recently described in rectal cancer treatment, with potential technical and oncologic advantages compared to transabdominal approach, especially in males.

The transanal approach for the proctectomy has been described also in IPAA since 2015, showing feasibility and potential technical advantages; some series and initial comparative studies have been published, showing a similar rate of postoperative morbidity, equivalent quality of life and functional results. The complete mesorectal excision is not requested for this indication, and is rarely performed in the described experiences.

The aim of our study is to analyze a single centre experience of transanal IPAA (Ta-IPAA), examining early postoperative complications, medium-term functional outcomes and quality of life.

Methods

In our Center the transanal approach for restorative proctocolectomy has been performed since August 2018. All epidemiological data were extrapolated from the hospital information system; a unique IBD database was set up. Baseline epidemiological characteristics of the patients were examined; the Mayo Score for UC was used to define the disease activity index. Enhanced Recovery After Surgery (ERAS) protocol was applied to all patients. Clavien-Dindo classification was employed to determine postoperative complications. Preliminary functional outcomes were assessed in the outpatient clinic, from 1 to 6 months after ileostomy reversal, with the use of validated questionnaires. Fecal incontinence for liquid or solid stool, restriction in work and social life were investigated with the use of the Wexner Continence Grading Scale at 1 and 6 mo after ileostomy reversal.

Genitourinary and sexual functions were also assessed through the International Erectile Function Score (IEFS-5) for males and Female Sexual Function Index (FSFI) for females 6 mo after ileostomy reversal. Quality of life was evaluated according to Fazio et al., using both the validated cleveland Global Quality of Life (CGQL) questionnaire, and the happiness with surgery, evaluated with a score from 0 to 10, with 10 representing complete satisfaction with the procedure.

The former is a simple score specifically designed for pelvic pouch patients surgery, investigating three items: the quality of life, quality of health and energy level. The scores were added and the final CGQL utility score was calculated dividing this result by thirty.

Surgical technique

A detailed description about the surgical technique and its variations is reported in the paper from Borja de Lacy et al. We report here a summary of the surgical procedure. The operation can be performed in two-steps (subtotal colectomy and transanal proctectomy with IPAA with diverting stoma in the first step, stoma closure in the second one) or three-steps (subtotal colectomy with end-ileostomy alone in the first
step, transanal proctectomy with IPAA and diverting stoma in the second step, stoma closure in the third one) according to the clinical conditions and choice of the patient23,24,25.

The abdominal phase can be performed using the laparoscopic or the open approach. The transanal phase starts with the introduction of a GelPoint Path® (Applied Medical, Rancho S. Margarita CA USA) with three working Ports and a standard 10 mms 30° laparoscopic camera to access the rectal lumen. A 0 Polypropylene purse-string suture is placed for rectal lumen closure, 4 cm above the dentate line, carbon dioxide is insufflated at a pressure of 12 mmHg to distend the rectal stump and the dissection field, and the proctotomy is started 1 cm distally. The specimen quality is not a performance indicator in proctectomy for UC, giving the chance to make close rectal dissection or intra-mesorectal dissection close to the bowel wall. This latest approach has the potential advantage to reduce the risk of pelvic nerve and urethral injury but could cause a more relevant blood loss.

Mesorectal dissection continues until the rectal surgeon “meets” the abdominal surgeon from the opposite direction. The specimen should be brought out through the Pfannenstiel mini laparotomy, transanally or through the pre-existing or future stoma site, according to the surgeon evaluation. In all cases, the wound is protected with a wound protector (Alexis®, Applied Medical, Rancho S. Margarita CA USA) which enables a laparoscopic approach through the extraction site before and after specimen retrieval, and is useful to prevent SSI26. A 12 cm long J-pouch is created extracorporeally with two loops of the small bowel. Another 0 Polypropylene purse-string suture is hooked on the distal rectal cuff. The end-to-end ileal pouch-anal anastomosis is created with a single circular stapler. The integrity of the anastomosis is evaluated through the reverse air leak test and ICG angiography can be performed to assess adequate mucosal and anastomotic perfusion. A loop ileostomy is created. The stoma closure represents the last phase of surgical treatment and it is performed after endoscopic evaluation of the pouch and pouch-anal anastomosis.

## Results

Between October 2018 and March 2019, in our Colorectal Surgery Unit, 8 patients affected by ulcerative colitis (UC) underwent laparoscopic restorative proctocolectomy (RPC) with combined transanal access (Ta-IPAA).

The median age was 54 years (range 28-79) (Table 1).

Six patients presented at the operation with moderate disease (6-10 Mayo score). Two patients presented at the operation with severe disease and required urgent surgery. One of them presented with toxic mega colon.

### Table 1. Clinical details at baseline

Six patients underwent three-steps and two patients two-steps procedure. In all cases the multi-portal laparoscopic approach was employed to achieve the subtotal colectomy. We had no cases of conversion
from laparoscopy to open surgery. The specimen was brought out through the Pfannenstiel mini laparotomy or through the stoma site in a single case. All patients had a single circular-stapled ileo-anal pouch anastomosis as described above. All patients received a defunctioning skin bridge loop right ileostomy\(^{27}\) (Table 2).

| Patient | Gender | Age     | BMI    | ASA | Mayo score |
|---------|--------|---------|--------|-----|------------|
| 1       | 1      | 50-60   | 20-25  | 3   | 8          |
| 2       | 1      | 70-80   | 20-25  | 3   | 9          |
| 3       | 2      | 50-60   | 30-35  | 3   | 9          |
| 4       | 1      | 60-70   | 20-25  | 3   | 10         |
| 5       | 1      | 20-30   | 20-25  | 2   | 9          |
| 6       | 2      | 50-60   | 25-30  | 2   | 12         |
| 7       | 2      | 50-60   | 20-25  | 2   | 12         |
| 8       | 1      | 50-60   | 25-30  | 2   | 9          |

Table 2. Surgical details and operative time of proctectomy and IPAA. For patients operated in II stages, the operating time includes the colectomy.

**Early post-operative complications**

According to Clavien-Dindo classification, postoperative complications were determined occurring within 30 days after surgery. One patient had urinary infection treated with antibiotic therapy after the second phase of surgery (Clavien-Dindo Grade II). One patient had ileus after both operations; fasting was the only therapy used (Clavien-Dindo Grade I). One patient, presented with toxic megacolon at the operation, had pulmonary infection (Clavien-Dindo Grade II). Only one patient required surgical intervention for a large parastomal hernia seven days after surgery (Clavien-Dindo Grade IIIb) (Table 3).
No cases of anastomotic leakage were found. Only one case developed a surgical site infection (SSI) graded Clavien Dindo II after the II surgical stage.

Table 3. Post-operative complications are recorded and classified according to Clavien – Dindo (16). Three-stage RPC [subtotal colectomy + proctectomy and ileal pouch-anal anastomosis (IPAA) + closure of ileostomy]; Two-stage RPC (total proctocolectomy and IPAA + closure of ileostomy); NA: not applicable

The median Length Of Stay (LOS) for the first phase of the three-stage surgery was 6,8 days (range 3-16). The LOS for the second phase of the three-stage surgery was 7 days (range 2-14). The LOS for the restorative proctocolectomy in two step surgery was 5,5 days. Pathological examination showed low-grade dysplasia in all patients. The loop ileostomy was closed at a median time of 6 months after RPC, according to the institutional protocol and case-load. Loop ileostomy take-down was performed with the pursestring technique and we report no postoperative complications.

Table 4. Patient reported outcomes
| Patient | Quality of life | The quality of health | Energy level | Final Score |
|---------|----------------|-----------------------|--------------|-------------|
| 1       | 7              | 5                     | 5            | 0.56        |
| 2       | 7              | 6                     | 8            | 0.70        |
| 3       | 4              | 8                     | 4            | 0.53        |
| 4       | 7              | 7                     | 6            | 0.66        |

Table 5. Details of Cleveland Global Quality of Life.

We also evaluated patients’ satisfaction about surgery. We asked patients to determine their “happiness after surgery” on a scale from 0 to 10, where 10 was the maximum. Happiness-with-surgery scores ranged from 7 to 10 (median 8) \(^{25}\).

Discussion

The transanal approach represents the newest option for restorative proctocolectomy (RPC), improving the technical steps of a complex operation and the surgical outcomes. Health-related quality of life for this type of patients is very important, considering their young age and life expectancy.

The technique was first described in human by the Barcelona team in 2015 after the initial animal and cadaveric experiences, with a first case series involving 16 cases\(^8\). Since then, we found in literature 5 single-case reports\(^{29,30,31,32,33}\), 4 further case series ranging from 8 to 18 cases\(^{9,10,11,12}\) and three multicentric experiences, reporting partially overlapping cohorts of 97\(^{13}\), 62\(^{34}\) and 100\(^{14}\) cases. Described cases vary in indication from IBD to FAP.

The transanal approach can be employed, both in cancer and IBD surgery, to overcome some limitations of the traditional minimally invasive techniques, thus allowing better visualization in the low pelvis and easier dissection of the distal 5 cm of the rectum.

Reported experiences agree that Ta-IPAA allows a better visualization of the distal 5 cm of rectum, making easier the identification of a <2 cm rectal cuff and a more precise pelvic dissection.
Stapled anastomosis is considered the gold standard\textsuperscript{5} and the length of the rectal cuff is one major determinant of quality of life after operation. A cuff length \(>2\) cm is related to symptomatic inflammatory disease recurrence or neoplastic risk, while a complete mucosectomy requests a colo-anal hand-sewn anastomosis which is associated with poorer continence, lower anal resting pressures and permanent loss of the recto-anal inhibitory reflex with consequent night-time soiling\textsuperscript{35}. To achieve a 2 cm rectal cuff, with the transanal approach we make a pursestring 4 cm proximal to the dentate line and make a rectotomy 1 cm distally. A further cm of rectal wall will be removed in the stapler donught, thus leaving the correct length of rectal stump, allowing a low risk of symptomatic disease and an optimal conservation of the anal sensitivity for a better continence. Moreover, Ta-IPAA permits the identification of the site for rectal section and the realization of a transanal distal pursestring, avoiding multiple stapler firings for rectal stump closure and lowering the risk of anastomotic leakage\textsuperscript{36}.

This technique in IBD treatment was employed only by few expert surgeons; moreover solid data concerning long term functional outcomes are still restricted. First functional data in a series of TaTME performed for rectal cancer\textsuperscript{37} showed preserved urinary and sexual function and low incidence and severity of LARS. De Buck van Overstraeten A. et al.\textsuperscript{13} published short-term outcomes of 97 patients from 3 Institutions who underwent a single incision surgery combined with TaTME for ileoanal pouch construction, compared with 119 cases in which a trans-abdominal approach was employed. They demonstrated the safety of Ta-IPAA for UC and showed a lower rate of 90 days postoperative complications in ulcerative colitis, comparing Ta-IPAA to Trans-abdominal approach.

A more recent paper\textsuperscript{14} reported a multicentric experience evaluating the long-term outcomes of Ta-IPAA against Abd-IPAA in restorative proctocolectomy, in 100 vs 274 cases. It shows that there are no statistically significant differences between Ta-IPAA and Trans-abdominal-IPAA considering quality of life and that Ta-IPAA is associated with higher quality of health and energy level. Furthermore, severe complication rate was significantly reduced, whereas anastomotic leak rate was non significantly lower with Ta-IPAA.

Quality of life and functional outcome are crucial issues in restorative proctocolectomy, and current results, although encouraging, report a rate of pouch failure up to 20% in 20 years experience\textsuperscript{38}. Technical refinements are therefore required in order to achieve better functional results. Many scales have been proposed to evaluate functional aspects in the main areas of continence, genito-urinary functions and general quality of life. In our initial experience we employed very simple, easy to administer questionnaires, in order to obtain a simple evaluation of the most important domains (Tables 4 – 5).

Our study presents several limitations. The first is related to the very small sample size, which is the reason we decided to make a non-comparative report. The absence of a comparative analysis makes impossible to draw any conclusion from our results, but only to confirm the feasibility of the technique, already demonstrated by others, and to point out the need or comparative studies

\textbf{Conclusion}
In conclusion, our small experience confirms preliminary data available showing that Ta-IPAA provides very good short- and medium-term functional results for ileoanal pouch surgery. The major limitation of our study is related to the small number of cases operated in a single center. More studies are needed to confirm our results.

Abbreviation

(TaIPAA) transanal protocolectomy and ileal pouch-anal anastomosis, (TaTME) transanal total mesorectal excision, (ERAS) Enhanced Recovery After Surgery, (UC) ulcerative colitis, (RPC) restorative proctocolectomy, (RPC) restorative proctocolectomy, (IBD) inflammatory bowel disease, (CGQL) Cleveland Global Quality of Life, (SSI) surgical site infection

Declarations

Ethics Approval and consent to partecipate: This study was reviewed and approved by the ethics committee of Campus Bio-Medico University of Rome. All procedures performed in studies involving human participants were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki Declaration and its later amendments or comparable ethical standards. Informed written consent was obtained from all individual participants included in this study

Consent for publication: Not applicable.

Availability of data and materials: The datasets used and/or analyzed during the current study are available from the corresponding author on reasonable request.

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Authors’ contributions: GTC, FC and ME contributions to study conception and design, data analysis and interpretation, and preparation of the manuscript. GM and SL participated in data collection and analysis. MC proofread and revised the manuscript. All authors read and approved the final manuscript.

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