



Are radiologic pouchogram and pouchoscopy useful before ileostomy closure in asymptomatic patients operated for ulcerative colitis?

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Abstract

Objectives Restorative proctocolectomy with ileal pouch-anal anastomosis (IPAA) is the “gold standard” procedure for patients with ulcerative colitis (UC) requiring surgical intervention. A de-functioning ileostomy is usually performed, as a step for the IPAA procedure. The aim of this study is to present the methodology and results of the routine double assessment of IPAA integrity in asymptomatic patients prior to the ileostomy reversal and evaluate its necessity.

Methods This is a retrospective study of 61 UC patients, who underwent IPAA construction, in 2010–2016. A diverting ileostomy was created after IPAA construction, which was reversed at least 3 months later. A double assessment, with pouchogram and pouchoscopy, of IPAA integrity was performed, before stoma closure. Post-operative symptoms and signs of complications, imaging studies, and endoscopic findings were recorded during follow-up.

Results Prior to the ileostomy reversal, both pouchoscopy and pouchogram identified no patient with evidence of anastomotic leakage. During a mean follow-up of 3.67 years after ileostomy reversal, 11 patients developed complications but only one had signs of leakage, which presented as a pouch-vaginal fistula. The specificity of both the pouchogram and pouchoscopy reached 100% and the negative predictive value ranged between 98.4 and 100%.

Conclusions The specificity of pouchoscopy and pouchogram prior to ileostomy closure, in asymptomatic patients with IPAA for UC, is very high in recognizing an intact anastomosis, but their combination did not alter the diagnostic accuracy or had any effect in further management. At least, pouchogram could be selectively performed only in patients with high-risk clinical indicators.

Key Points

- *The double assessment of ileal pouch-anal anastomosis with pouchogram and pouchoscopy, prior to ileostomy closure, specifically in patients with ulcerative colitis has not been evaluated before.*
- *The specificity of pouchoscopy and pouchogram prior to ileostomy closure, in asymptomatic patients with IPAA for UC, is very high in recognizing an intact anastomosis.*
- *However, their combination did not alter the diagnostic accuracy or had any effect in further management, in asymptomatic patients.*

Keywords Ileal pouch-anal anastomosis · Endoscopy, gastrointestinal · Fluoroscopy · Ulcerative colitis · Proctocolectomy, restorative

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Abbreviations

| | |
|----------|--|
| IC | Ileostomy closure |
| IPAA | Ileal pouch-anal anastomosis |
| MD CT | Multi-detector computerized tomography |
| MRE | Magnetic resonance enterography |
| MRI | Magnetic resonance imaging |
| <i>n</i> | Number of cases |
| NPV | Negative predictive value |
| PES | Pouchoscopy |
| PPV | Positive predictive value |
| Q | Quartile |
| SD | Standard deviation |
| UC | Ulcerative colitis |

WCE Contrast pouchogram-water-soluble contrast enema study

Introduction

Restorative proctocolectomy with ileal pouch-anal anastomosis (IPAA) remains the “gold standard” surgical treatment in patients with ulcerative colitis (UC) and familial adenomatous polyposis. Complication rates such as pelvic sepsis due to anastomotic leak, fistula or stenosis, pouchitis, and Crohn’s-like disease in the ileal pouch vary from 19 to 54% according to different centers [1, 2]. Regarding UC, leakage is reported from 5 to 19% in various studies [3].

The integrity of the IPAA, in asymptomatic patients prior to ileostomy closure, is usually assessed, with a combination of history and clinical examination, pouchoscopy (PES), and pouchogram/water-soluble contrast enema study (WCE). More advanced image investigations, such as computerized tomography enterography, abdominal/pelvic magnetic resonance imaging (MRI) [4, 5], or magnetic resonance enterography (MRE) [6], are used in complex cases with suspicion of complications.

However, there are no clear guidelines and it is not well documented which is the best method to identify complications in asymptomatic patients. Several authors [7–12] question the need of image investigations of the anastomosis before the ileostomy closure (IC) in patients with cancer but we have not found enough evidence for patients with IPAA and UC.

Since UC is primarily restricted to the large bowel, someone might expect that IPAA will enable eradication of diseased mucosa and cure for UC [13]. However, those patients do develop complications and inflammation at the pouch (pouchitis), or at the rectal mucosa remnant (cuffitis) or Crohn’s-like disease of the pouch.

The aim of our study was to evaluate the need of double assessment of IPAA with pouchogram and flexible pouchoscopy, before ileostomy closure, in asymptomatic patients operated for UC. Moreover, we investigated whether the double assessment could recognize a clinically silent anastomotic deficit that may lead to active pelvic sepsis after ileostomy reversal.

Materials and methods

This is a retrospective study of 61 out of 67 patients with UC (Table 1), who were treated surgically (Table 1). Patients underwent either a two-stage procedure (proctocolectomy with J-shaped IPAA and diverting ileostomy followed by IC) or a three-stage procedure (subtotal colectomy with end ileostomy, followed by proctectomy and J-shaped IPAA with diverting ileostomy followed by IC) between 2010 and 2016, at Aretaieion University hospital. Patients without valid data,

or those who were lost in follow-up, or declined to participate in the study, were excluded from further analysis (6 patients).

Pre-operative (before closure of the de-functioning ileostomy) imaging studies and endoscopic findings, as well as post-operative symptoms and signs of complications, were reviewed for a 3-year follow-up period and tabulated. Pouchoscopies and pouchograms were performed 3 months following IPAA, with a view to reverse the de-functioning ileostomy. All patients were asymptomatic.

Radiologic leakage was defined as the presence of contrast leakage or a fistula formation at the area of anastomosis. The doctors were not blinded to the patient’s history and interpreted the examinations as per routine protocol.

Approval was obtained by the hospital’s scientific committee and patients were included after obtaining informed consent. An experienced colorectal surgeon (IP) was in charge during every surgical and radiological procedure.

Surgical technique

The IPAA procedure [14] involves a conventional total abdominal colectomy, proctectomy, construction of the ileal pouch, and ileoanal anastomosis. There are various designs of an ileal pouch such as the J-pouch, double J-pouch, triple S-pouch, and quadruple W-pouch. The preferred pouch design in our department is the J-shaped pouch. The entire procedure can be performed in one operation, but it is usually split into two or three stages depending on the patient’s health status, severity of disease, prolonged intake of steroid medication, and surgeons’ judgment at the time of operation. In the two-stage procedure, the first step involves a proctocolectomy and fashioning of the pouch with a formation of de-functioning loop ileostomy which is closed 3 months later, allowing the newly constructed pouch to heal without intestinal contents passing through it [15]. A three-stage procedure involves initially a subtotal colectomy with an end ileostomy, followed by a completion proctectomy, pouch fashioning, and de-functioning ileostomy and a final third step for closing the ileostomy.

Flexible pouchoscopy technique—diagnostic and therapeutic

Pouchoscopy [16] was performed by the operating surgeon usually on the same day as the pouchogram, which it always preceded. Total duration of the procedure was 10 to 15 min. Instructions were given to all patients prior to the procedure and written consent was obtained. We used a standard colonoscope with 2% lignocaine gel and the procedure was well tolerated in all cases, with no need for sedation.

A digital rectal examination was performed prior to pouchoscopy, as severe pain may suggest ulceration or focal inflammation. At an average distance of 2 cm from the dentate

Table 1 Demographic and clinical data. *SD* standard deviation, *Q* quartile, *n*, number of cases

| Patients' characteristics | Values |
|--|-----------------------|
| Age | |
| Mean \pm SD | 38.2 \pm 16.7 years |
| Median (Q1–Q3) | 35 (26–50) |
| Range | 14–71 |
| Gender, <i>n</i> (%) | |
| Male | 39 (64%) |
| Female | 22 (36%) |
| Procedure | |
| Two-stage | 46 |
| Three-stage | 15 |
| Type of anastomosis | |
| Stapled | 60 |
| Hand-sewn | 1 |
| Pouchogram–pouchoscopy | |
| Negative | 61 |
| Positive (for leak) | 0 |
| Follow-up (mean \pm SD) | 3.67 \pm 1.07 years |
| Complications in follow-up (post-ileostomy closure) | 11/61 (18%) |
| • Pouchitis | 5 |
| • Abscess (not related to surgery), pelvic collections | 2 |
| • Ileus | 3 |
| • Fistula (poucho-vaginal) | 1 |
| Type of IPAA process in patients with post-operative complications (<i>p</i> value 0.8) | 11/61 (18%) |
| Two-stage | 8/46 |
| Three-stage | 3/15 |

line, we assessed the anastomosis, which feels like a discrete ring of fibrous connective tissue. Inability for the index finger to pass through may reflect a degree of stenosis. The colonoscope was then inserted and under direct vision, we looked for signs of mucosal inflammation below the anastomosis, which could be compatible with “cuffitis”. At the IPAA (Fig. 1a–c), we looked for areas of stricture, necrosis, or breakdown. We expected to see the typical “owl eyes” view in a healthy pouch (Fig. 1a). Routine biopsies are not taken, unless otherwise indicated; e.g. endoscopic findings suggesting the presence of inflammation at the pouch (in order to discriminate between different etiological entities, like pouchitis, Crohn's disease, and collagenous pouchitis) or neoplasia. In cases of anastomotic strictures, we performed manual dilatation (gentle digital dilatation).

Pouchogram-fluoroscopic water-soluble contrast enema study

No preparation was required before the examination, since all patients had a de-functioning ileostomy. All pouchograms were performed on a digital fluoroscopy system (Luminos Fusion; Siemens Healthineers, Erlangen, Germany) via a low-pressure, water-soluble contrast diatrizoate (100 ml gastrografin in 180 ml 0.9% sodium chloride) enema just before the ileostomy closure. A gastrointestinal consultant radiologist (VK) and a colorectal surgeon (IP) performed the examinations and reviewed the results in consensus. In our cohort, no cases of discrepancies were recorded. Pouchograms were always performed subsequent to pouchoscopies, either on the same day or within 2 days.

Both anteroposterior and lateral scout radiographs were obtained in all cases, to map all the radiodense structures (including bowel sutures) that may mimic extraluminal leakage of contrast, as well as to assess the amount of air within or behind the pouch. A 12F Foley catheter was then inserted into the pouch, which was subsequently filled with small quantities of contrast; fluoroscopic guidance was used, both in antero-posterior (Fig. 2a) and lateral plane (Fig. 2b). In cases where no opacification of the intestinal lumen was noted, the patient was asked to perform a Valsalva maneuver. The Foley catheter was then removed, and the patient was asked to evacuate the pouch contents. We assessed the post-evacuation residue to rule out leaks, as sometimes these are detected only during forced evacuation [17].

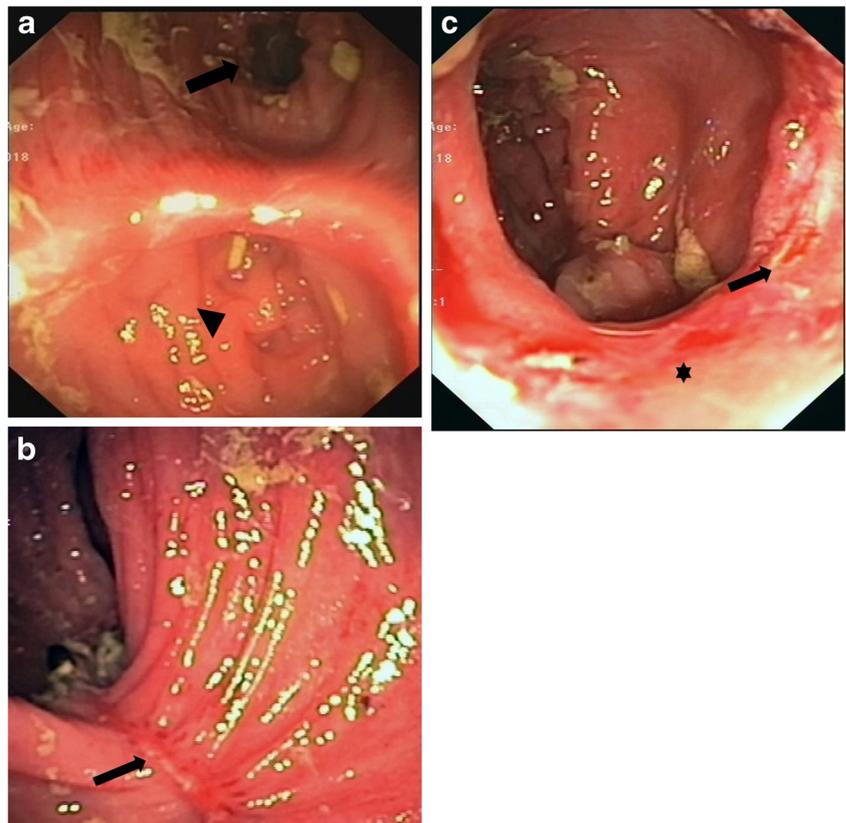
Results

This study included 61 patients with UC that had restorative proctocolectomy with IPAA. The mean age of these patients was 38.2 years and the majority of them were male (64%). Forty-six patients (75.4%) underwent a two-stage procedure, while a three-stage procedure was decided for patients with acute severe colitis resistant to rescue therapy or prolonged use of corticosteroids. The anastomosis was fashioned with a stapling device for the majority of patients (98.3%) (Table 1). We faced minor complications after IPAA surgery (e.g., wound infections, post-operative ileus conservatively treated). Two patients were suspected for leakage after IPAA operation due to changes in drain content, but they were not further evaluated since they were asymptomatic, and the drained content had turned to clear, serum-like fluid prior to drain removal.

Pre-operatively, both pouchogram and pouchoscopy were negative for leakage or pouchitis in all 61 patients and subsequently the ileostomy was reversed.

During the post-operative period, with mean follow-up of 3.67 years, 50/61 cases (82%) showed no immediate or delayed complications. However, 11/61 (18%) patients developed various complications; 8/11 patients had a two-stage

Fig. 1 **a** Pouch endoscopy. Typical “owl eyes view” in a healthy pouch. Afferent limb (arrow) and efferent limb (arrow-head). **b** Pouch endoscopy. Anterior stapled line of the J-pouch (arrow). **c** Pouch endoscopy. Endoscopic view of ileoanal anastomosis (arrow) and rectal cuff (star)



and 3/11 had a three-stage procedure (Table 1). Ileus presented in three patients 1 year following reversal of ileostomy, requiring laparotomy and adhesiolysis. There were three cases of acute pouchitis, which were diagnosed 2 years after closure of the ileostomy and resolved with a short course of per os ciproxin and/or metronidazole. Two patients presented with chronic refractory pouchitis (resistant to antibiotics and anti-TNF agents). Thus, a diverting ileostomy was created for both of them, 1 and 3 years after initial ileostomy closure, respectively. One female patient developed pelvic collections that were drained under CT guidance image guidance and another patient was diagnosed with a tubo-ovarian abscess, secondary to acute endometritis, not related to IPAA surgery. Another

female patient, 14 months after closure of the ileostomy, presented with hematochezia during her menstruation, raising the suspicion of a pouch-vaginal fistula that was confirmed with a repeated pouchogram (Fig. 3). That showed contrast in the vagina deriving from a fistula between the anterior wall of the pouch and the posterior wall of the vagina, best seen in the oblique view (Video 1).

The specificity of double assessment for the recognition of intact anastomosis was very high, reaching 100%. However, the only patient with pouch leakage (pouch-vaginal fistula) was not recognized prior to stoma closure, and so we cannot derive conclusions from the calculated sensitivity. The negative predictive value (NPV) of both the pouchogram and

Fig. 2 Normal pouchogram of a 34-year-old female performed before the ileostomy reversal **a** anteroposterior and **b** lateral view. The anteroposterior view will ensure detection of possible anterolateral leaks. Most leaks are better seen on the lateral view

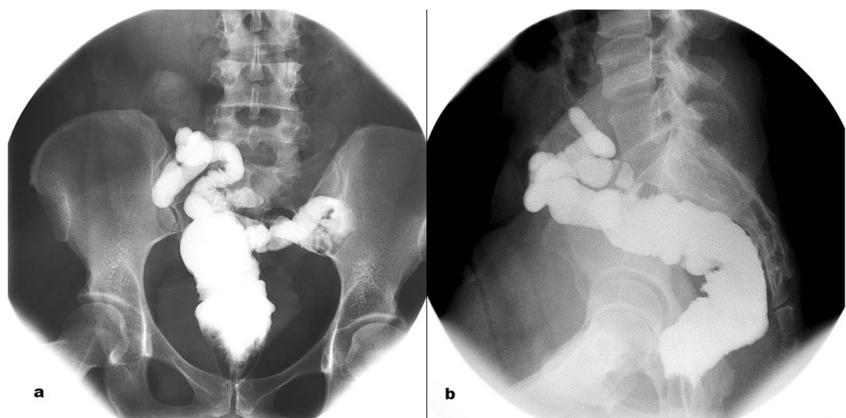
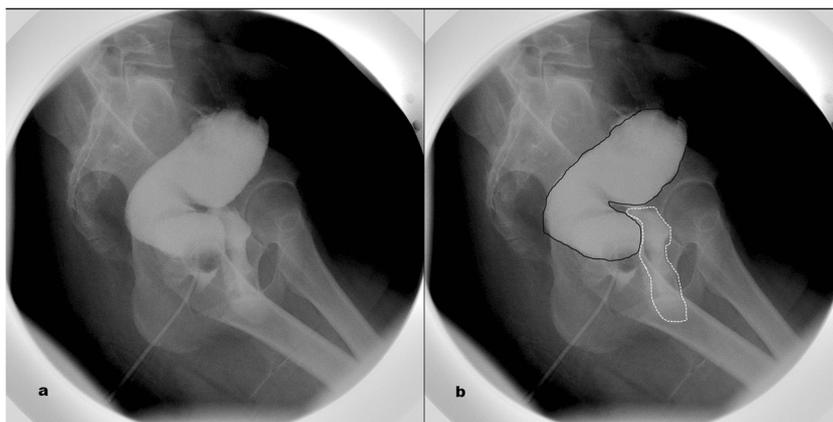


Fig. 3 a, b Pouchogram (lateral view) of a 16-year-old female performed 14 months after closure of the ileostomy. There is opacification of both the pouch (black line in **b**) and of the vagina (white line in **b**), indicating the presence of a poucho-vaginal fistula



pouchoscopy, in our cohort, ranges from 98.4 to 100% (the lower percentage corresponds to the hypothesis that the pouch-vaginal fistula pre-existed and the pre-operative assessment failed to depict the underlying pathology). As we had no cases that pre-operatively were diagnosed with leak, the positive predictive value (PPV) cannot be calculated. The combination of the diagnostic modalities did not affect the overall diagnostic value.

Discussion

Anastomotic leak-sinus is an infrequent complication following IPAA, with an incidence of 2.6–19% [1, 3, 18–20]. Although diverting ileostomy does not seem to reduce leak rates according to a recent large retrospective study [21], pelvic sepsis is more easily controlled when the pouch is defunctioned. So, the integrity of the anastomosis before stoma closure is essential since a well-functioning IPAA is associated with improved quality of life [22] and pelvic sepsis is a major cause for poor functional outcome and future pouch failure [23]. Redo pouch surgery, even in high-volume centers, is a demanding and challenging procedure associated with higher rates of failure than primary operation [24].

A multicenter evaluation for anastomotic leakage by Sahami showed that there are several independent risk factors for complications, such as obesity and BMI score > 25, ASA score > 2, duration of the disease for at least 5 years, and treatment with steroid and anti-TNF, with a different risk profile for one-stage proctocolectomy and completion proctectomy procedures [20].

Nowadays, following the two- or three-stage proctocolectomies, before IC, the anastomosis is usually evaluated with a combination of history, clinical-digital rectal examination, pouchoscopy, and pouchogram. When there is an anastomotic leak, most of the times, the patient will have clinical symptoms and signs, such as guarding, tachycardia, high temperature, and elevated inflammatory markers, and urgent imaging with CT is mandatory. Rarely, the leakage might be

asymptomatic, forming blind “sinuses,” arising from the anastomosis, secondary to poor healing. These are most often diagnosed at the time of pouchography and a repeat examination is recommended 3–6 months later; if the sinus track is narrowed or obliterated, then IC can be performed [1].

The use of pouchogram was suggested back in 1970s [14, 18]. Since then, CT, MRI, and MRE [25] have also been used in this setting and several authors have compared the diagnostic value and accuracy of each modality [17, 25, 26]. Without doubt, image assessment of the pouch before IC provides a thorough approach, but it may delay surgery. Moreover, pouchogram causes additional discomfort and radiation exposure, in relative young patients that have previously been exposed to diagnostic imaging procedures with ionizing radiation due to their underlying disease. The question, thus, remains if double assessment should be performed as standard practice in all patients (with or without risk factors of leakage).

Indeed, there is controversy in literature, whether a pouchogram needs to be performed prior to IC. Published papers on the subject included patients who underwent low-anterior resection, most commonly for rectal cancer, with colonic J-pouch [7, 8, 10–12, 27] and there is not enough information with regard to UC, which might influence the outcome of the anastomosis. To our knowledge, there are no sufficient data regarding anastomotic leak rate differences between UC patients and oncologic patients. Moreover, extrapolating results from studies of oncologic patients to UC patients are probably not appropriate since difficulties, such as matching up patients (oncologic patients are older with more comorbidities and possibly under the adverse effects of adjuvant or neo-adjuvant treatments, whereas UC patients are often malnourished), cannot be easily overcome.

In our cohort, we evaluated the need of double assessment of the pouch prior to the IC in patients with UC. In all enrolled patients, no clinical, radiological, or endoscopic findings of leakage were identified prior to IC. During follow-up, 11 patients developed complications but only in one patient it was related to pouch leakage, with clinical symptoms suggestive of a pouch-vaginal fistula, that occurred 14 months after the

IC. This patient was not considered high risk for anastomotic leak complications; she was well-nourished, without anemia, and not receiving steroid medication, whereas the anastomosis was performed without tension under good blood supply. The time interval increases the possibility that the fistula might have developed subsequently and it is less likely that a latent post-operative leakage was present before IC. Therefore, the NPV of double assessment of IPAA with pouchogram and pouchoscopy prior to IC, in asymptomatic patients with UC, ranges from 98.4 to 100%. The pouchoscopy additional to the pouchogram did not alter the diagnostic accuracy nor had any effect in further management. Although the specificity and NPV are high, we cannot calculate the PPV, since no patients were diagnosed with leakage. We cannot derive conclusions from the calculated sensitivity, since there was only one patient with pouch leakage.

Even though our study does not include a large number of cases, based on our observations and results, we question the need of double assessment as routine practice in the asymptomatic patients undergoing IPAA for UC prior to ileostomy closure. Although the digital rectal examination was negative, all 61 patients were exposed to ionizing radiation secondary to pouchogram with additional inconvenience. As several authors state [7–12, 20, 28], patients with high-risk clinical indicators for developing anastomotic leakage might be of more benefit when the IPAA is double-assessed prior to ileostomy closure, since diagnosis of an asymptomatic leakage might change their management.

In a PubMed search, we found no studies evaluating the integrity of the ileal pouch prior to ileostomy closure in patients specifically with UC, with the double-assessment process as described in our project. There are a few papers, though, highlighting the importance of imaging in order to assess the anastomosis in patients who underwent low-anterior resection and de-functioning ileostomy for rectal cancer.

Da Silva et al [10] reviewed 84 patients that underwent a colonic J-shaped pouch for adenocarcinoma, villous adenoma, low stricture, and recto-vaginal fistula and had evaluation of the integrity of the pouch with a pouchogram and the results were compared with patient's clinical outcome following ileostomy closure. Although the specificity was high, it showed an overall low sensitivity (25%) to predict complications and only in one case, the pouchogram actually changed management.

Similarly, in a prospective audit by Jeyarajah et al [11], the specificity of pouchogram was low, with high false positive cases but since it changed management in 7.9% of their patients, they suggested that some imaging is still indicated in patients at risk.

Seo et al [27] evaluated the efficacy of WCE in accurately predicting anastomotic healing, identifying four different types of radiologic leakages on a WCE (dendritic, horny, sacular, and serpentine type). Although they concluded that a routine WCE appears to be helpful for detecting radiologic leakage, the importance of this investigation in changing

patients' management was not mentioned. Overall, WCE revealed leakage in 20 patients (out of 682) which corresponds to the 2.9% of all patients and to the 0.9% of asymptomatic patients. From their manuscript, we derive the conclusion that in asymptomatic patients, the benefit of performing a pouchogram is small, and even in the symptomatic patients, the sensitivity of identifying the leakage is low.

Lawal and et al [9] did a literature review regarding the routine use of WSE to assess the integrity of the IPAA and they also concluded that there are not enough data supporting its necessity. Findings were normal in 89.7% of their cases and showed stricture in 6.9%. There was a leak in only one case (3.4%) which was suspected in clinical examination. They do recommend the use of contrast enema only in symptomatic patients where a leak is suspected, thereby limiting radiation exposure and inconvenience.

Karsten et al [8] did a 10-year retrospective review in patients who had a WCE before taking down the diverting ileostomy for low pelvic anastomosis and also concluded that routine use of WCE has no significant impact on patient management. They found that WCE had false positive results, while findings such as strictures are often not clinically significant and might not necessarily change management. However, they suggest that it could be used only selectively in asymptomatic patients with high-risk clinical indicators, such as post-operative complications or previous leaks. Similar conclusions have been published by Hong et al [7] who analyzed the importance of barium enema in order to assess colorectal anastomosis prior to ileostomy closure.

With regard to sensitivity and specificity of the pouchogram, Alfisher et al [29] reported that using water-soluble agents can miss tiny fissures and small leaks, leading to false negative studies. For this reason, they used barium contrast in asymptomatic patients with negative digital rectal examination and normal pouchoscopy (as barium is contraindicated in cases with suspicion of leakage).

WCE studies may have also false negative results when the leakage or fistula is located in the anterior wall of the pouch or at the level of the ileoanal anastomosis, as it is difficult to demonstrate it when the patient is lying in the supine position with the contrast pooling towards the posterior portion of the pouch. If there is an air bubble in the anterior portion of the pouch or inadequate quantity of the contrast coating, the patient's position needs to be changed [29].

Tang et al [30] evaluated the sensitivity of both pouchogram and digital rectal examination in the assessment of anastomotic healing. Although, in their series with the 195 patients, 10 were diagnosed with UC, it was not clarified if those were found to have more complications than the others did. The overall sensitivity of the digital rectal examination in the detection of anastomotic pathology was 98.4%. Pouchogram was inaccurate in 20 patients and it only showed more information than digital rectal examinations in three patients who had a fistula. They concluded

that digital rectal examination is a useful complementary examination to pouchogram in the assessment of anastomotic integrity, if not superior and more reliable. A similar study by Karsten et al [8] showed that both pouchogram and digital rectal examination have equal sensitivity that reached the 100% and they suggested that pouchogram should be only used in the specific cases when the digital rectal examination has abnormal findings.

Pouchoscopy is considered the most useful tool and principal investigation for differential diagnosis in patients with pouch dysfunction after the closure of the de-functioning ileostomy. Navaneethan et al [28] did a MEDline review between 1982 and 2010 and found that pouchoscopy is the main modality in diagnosis and differential diagnosis of pouch dysfunction after closure of the ileostomy. In concordance with this study, Ouro et al [31] published a study with 121 patients who experienced pouch dysfunction following restorative proctocolectomy predominantly (93%) for UC. Eighty-six percent of these patients described their symptoms several months post-closure of the de-functioning ileostomy and flexible pouchoscopy was the principal investigation of choice, which helped in establishing a diagnosis. However, there is a dearth of literature examining the importance of performing a pouchoscopy examination prior to the closure of the de-functioning ileostomy in order to assess the integrity of ileoanal anastomosis. We have found a recently published paper by Cai et al [32] that, similarly to us, tried to evaluate the importance of routine perform of pouchoscopy prior to ileostomy takedown in asymptomatic patients with chronic ulcerative colitis, and they concluded that it could only be instrumental in specific patients who are suspected for complications.

Limitations

This study is limited by its small sample size. However, as the incidence of UC with pouch formation is not high, it would be challenging to evaluate much larger cohorts. PPV cannot be calculated, as our cohort had no cases with asymptomatic leakage. We found no studies in the literature evaluating the necessity of both pouchogram and pouchoscopy in patients with UC and IPAA before the IC, and therefore we cannot compare our findings. This lack of uniform practice limits the generalizability of our study results. Both the radiologist and surgeon were not blinded to patients' history, and that could be an observation bias. Finally, this is single-unit data, which would also limit the applicability of any recommendations.

Conclusion

The specificity of pouchoscopy and WCE prior to ileostomy closure, in asymptomatic patients with IPAA and underlying UC, is very high in recognizing an intact anastomosis, but

their combination did not alter the diagnostic accuracy nor had any effect in further management.

Additionally, to a thorough history and clinical examination including digital rectal test, pouchoscopy could be used to assess the integrity of the pouch prior to IC. As there is limited data in the literature, more studies are needed to further support its necessity. In line with many authors, we believe that pouchogram should be performed in the case of the following two scenarios: patients with signs and symptoms of anastomotic leakage and asymptomatic patients with findings in digital rectal examination or pouchoscopy indicating anastomotic deficit.

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Compliance with ethical standards

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Statistics and biometry No complex statistical methods were necessary for this paper.

Informed consent Written informed consent was obtained from all subjects (patients) in this study.

Ethical approval Approval was obtained by hospital's scientific committee.

Methodology

- Retrospective
- Diagnostic or prognostic study
- Performed at one institution

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