


Review of long-term complications and functional outcomes of ileoanal pouch procedures in patients with inflammatory bowel disease

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Introduction

Inflammatory bowel disease (IBD), inclusive of Crohn's disease (CD) and Ulcerative Colitis (UC), affects ~1 in 153 Australians.¹ First line management of IBD is medical therapy with immunosuppressive and/or biologic agents. When medical therapy fails, surgical treatment is considered. In acute severe UC or chronic active UC refractory to medical therapy, proctocolectomy with ileoanal pouch procedure (IAPP) is the preferred continence-sparing surgical option.^{2,3} IAPP is rarely performed to treat CD due to recurrent inflammation in the afferent limb of the ileum.⁴ Nowadays, J-Pouches are the preferred IAPP for surgical simplicity and improved functional outcomes.⁵

Abstract

Background: In medically refractory Ulcerative Colitis (UC), proctocolectomy with ileoanal pouch procedure (IAPP) is the preferred continence-preserving surgical option. Functional outcomes post-surgery and long-term complication rates in the biologic era remain ambiguous. This review primarily aims to provide an update on these outcomes. Secondly, risk factors associated with chronic pouchitis and pouch failure are explored.

Methods: Two online databases (MEDLINE and EMBASE) were searched on 4 October 2022 for English studies from 2011-present relating to long-term outcomes of IAPP in inflammatory bowel disease (IBD) patients. Adult patients with 12 month follow-up were included. Studies focused on 30-day post-operative outcomes, non-IBD patients or studies including less than 30 patients were excluded.

Results: Following screening and full-text review of 1094 studies, 49 were included. Median sample size was $n = 282$ (IQR: 116–519). Median incidences for chronic pouchitis and pouch failure were 17.1% (IQR: 12–23.6%) and 6.9% (IQR: 4.8–10.8%), respectively. Upon multivariate analysis, chronic pouchitis development was most significantly associated with pre-operative steroid use, pancolitis and extra-intestinal IBD manifestations, whilst pouch failure was most significantly associated with pre-operative diagnosis of Crohn's disease (compared to UC), peri-operative pelvic sepsis and anastomotic leak. Overall patient satisfaction was very high with four included studies reporting greater than 90% satisfaction rates.

Conclusion: Long-term complications for IAPP were common. However, despite this, patient satisfaction post-IAPP was high. Up-to-date knowledge of complication rates and their risk factors improves pre-operative counselling, management planning and patient outcomes.

Despite the restorative proctocolectomy with IAPP becoming widely adopted, questions regarding long-term complications and the functional outcomes for patients remain. Inflammatory pouch complications such as pouchitis, cuffitis and Crohn's disease of the pouch (CDP) are the most common chronic complications. All have significant impacts on long-term pouch outcomes. However, due to varied diagnostic criteria and definitions in the literature, reported complication incidences are highly variable.^{4,6–8} Similar inconsistencies are seen in reporting pouch failure rates and patient quality of life outcomes post-operatively.^{8,9}

Detail regarding long-term pouch outcomes and the identification of complication risk factors will assist clinicians in patient selection

for IAPP whilst improving patient counselling pre-operatively. This review primarily aims to provide an update on the incidence of long-term pouch complications including chronic pouchitis, pouch failure, cuffitis, CDP, pouch neoplasm, pouch fistula, pre-pouch ileitis (PPI), ongoing medical therapy, patient quality of life and bowel function post-operatively in the biologic era. Short-term outcomes such as 30-day post-operative complication rates will not be discussed. A secondary aim is exploring risk factors associated with pouch complications and pouch failure.

Methodology

Databases and search strategy

On 4 October 2022, two online databases (MEDLINE and EMBASE) were searched for English language publications from 2011-present. The search strategy was constructed by EW and YH and focused on three main themes: long-term pouch complications and functional outcomes, types of ileoanal pouch procedures and IBD.

The 'adj5' proximity operation was utilized to limit broader complications such as fistula or failure, to those specifically pouch related. As the review's focus is on long-term outcomes, acute post-operative complications like anastomotic leak and pelvic sepsis were not searched for. Such known predictors of poor pouch outcomes were not specifically searched for as there was no intention to report such incidences. Any relevant risk factors significantly associated with poor pouch prognosis would be captured by the comprehensive review of studies reporting long-term complication incidences alongside multivariate risk factor analysis.

Inclusion and exclusion criteria

Studies containing adult IBD patients (UC, CD and indeterminant colitis) who underwent IAPP with at least 1 year of follow-up were included. Patients >18 years old at the time of surgery were defined as adult. Description of incidence of long-term complications and/or quality of life or functional outcomes post-IAPP was required for inclusion. We define 'long-term' as complications reported >30 days after IAPP or closure of ileostomy for patients with a loop ileostomy formed at the time of IAPP. Studies reporting quality of life and functional outcomes post-IAPP had to have a non-IAPP IBD control group as a comparator (rather than the general healthy population). Multivariate analysis of risk factors associated with complications was required for inclusion.

Systematic reviews were excluded to avoid data duplication along with case reports and case series with less than 30 patients. Studies containing patients with IAPP indications other than IBD were excluded. Papers focused solely on 30-day post-operative complication rates, were excluded as this review focused on long-term complications and functional outcomes.

As heterogeneity of complication definitions exists within the literature, studies without clear definitions, particularly distinction between acute and chronic pouchitis, were excluded. In this review, we defined chronic pouchitis as an episode of inflammatory symptoms lasting greater than 4 weeks.

Results

Study selection

The final search of MEDLINE and EMBASE yielded 672 and 950 papers respectively, totalling to 1622 studies. Covidence was utilized for duplicate removal, title and abstract screening, full-text review and data extraction. Following duplicate removal, 1094 studies remained. Studies were screened by a single reviewer (YH).

Upon title and abstract screening, 859 studies did not meet inclusion criteria leaving 235 papers for full-text review. Relevancy was based on studies focused on long-term outcomes of IAPP in IBD patients only; not pathophysiology or management of IAPP complications or acute post-operative complications.

Following full-text review using our established inclusion and exclusion criteria, 49 studies remained for data extraction. Table S1 contains the complete inclusion and exclusion criteria. A PRISMA diagram summarizing the screening and full-text review process, including reasons for exclusion, is depicted below (Fig. 1).

Study characteristics

Of the included 49 studies, all but six were single centre retrospective studies. Other studies included were multicentre retrospective,^{10,11} multicentre cross-sectional,^{7,12} multicentre case-control,¹³ single centre case-control¹⁴ and single centre cross-sectional.¹⁵ Sample sizes of included studies range from 31 to 3672 (median = 282) across 13 countries with a mean follow-up time of 8.6 years.

Incidences of long-term complications

All data extracted reporting incidence of long-term complications and post-operative medication use is found in Tables S2 and S3 respectively.

Chronic pouchitis

Fifteen studies reported incidences of chronic pouchitis. This included chronic antibiotic refractory pouchitis (CARP) and chronic pouchitis that resolves after at least 4 weeks of antibiotics.

Reported chronic pouchitis incidence ranged from 7.3% to 31% (median 17.1%, IQR: 12–23.6%) with a mean follow-up time of 9.8 years.^{4,6,7,15–26}

Pouch failure

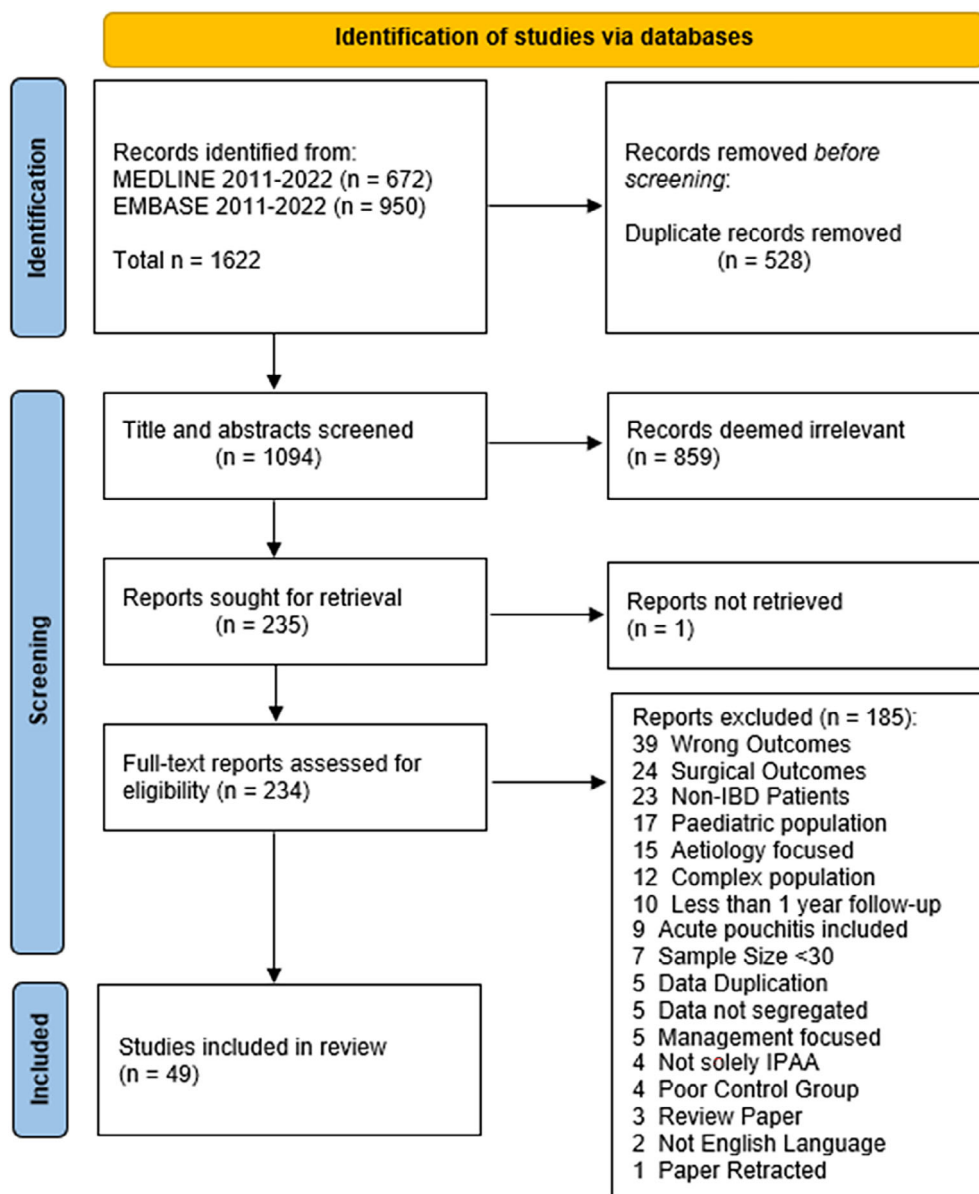
Nineteen studies reported incidences of pouch failure defined as the need for a permanent ileostomy with or without pouch excision.

Reported pouch failure incidence ranged from 1.6% to 18.9% (median 6.9%, IQR: 4.8–10.8%) with a mean follow-up time of 9.9 years.^{4,6,7,11,14,16,17,22,24,26–35}

Neoplasm of the pouch

Four studies reported incidences of neoplasm of the pouch defined as pouch dysplasia or cancer confirmed on biopsy.

Fig. 1. PRISMA diagram.



Reported neoplasm of the pouch incidence ranged from 0.35% to 3.3% (median 1.765%, IQR: 1.025–2.565%) with a mean follow-up time of 9.8 years.^{6,10,36,37}

Pouch fistula

Twelve studies reported incidences of pouch fistula defined as pouch fistula visualized via pouchoscopy.

Reported pouch fistula incidence ranged from 2.5 to 15.8% (median 11.3%, IQR: 5–13.7%) with a mean follow-up time of 10.1 years.^{4,6,7,16,21,24,26,29,32,33,35,38}

Crohn's disease of the pouch (CDP)

Nine studies reported incidences of CDP defined as Crohn's-like pathology (fistula, stricture and/or inflammation) on pouchoscopy.

Reported CDP incidence ranged from 7.8% to 20.9% (median 15.2%, IQR: 10%–18.75%) with a mean follow-up time of 8.4 years.^{6,7,16,17,26,28,35,39,40}

Cuffitis

Four studies reported incidences of cuffitis defined as clinical symptoms characteristic of cuffitis as well as endoscopic evidence of inflammation of the remnant rectal cuff.

Reported cuffitis incidence ranged from 8.0% to 30.1% (median 11.35%, IQR: 8.55–21.85%) with a mean follow-up time of 6.2 years.^{7,19,26,35}

Pre-pouch ileitis (PPI)

One study reported incidence of pre-pouch ileitis (PPI) as 6%,¹³ defined as mucosal inflammation proximal to the pouch mucosa.

Ongoing medical therapy post-operatively

The need for drug therapy post-IAPP was not widely reported.

Post-operative corticosteroid use was reported in 5/49 studies, ranging from 4.5% to 30% (median 13%, IQR: 8.15–21.9%),^{12,15,22,41,42} whilst only one paper reported post-operative antibiotic use at 28.7%.⁴¹

Five studies reported rates of post-operative biologic use ranging from 5.8% to 33.0% (median 10%, IQR: 6.4–21.9%) with a mean follow-up of 9.4 years.^{15,22,28,41,42}

Six studies reported incidence of post-operative immunosuppression use ranging from 3% to 15.5% (median 6.75%, IQR: 3.2–9.3%) with a mean follow-up of 9.4 years.^{15,22,28,41,42}

Many patients post-IAPP remained on motility agents (loperamide, cholestyramine and domperidone), with rates reported as 47%,⁴³ 50%,⁴⁴ 66.2%³² and 68.8%.⁴⁵ Nyabanga *et al.*⁴¹ reported approximately a third of patients used probiotics or NSAIDs post-operatively, whilst Netz *et al.*²² reported nearly half (47%) of IAPP patients required some sort of medication post-operatively.

Functional and quality of life outcomes

Reporting of functional and quality of life outcomes post-IAPP varied considerably. This review focused on bowel function, overall patient satisfaction and quality of life. Table S4 contains all data extracted on functional and quality of life outcomes.

Bowel function post-IAPP was variable. Many patients still experienced frequent daytime bowel motions with 45% (IQR: 36–85%) experiencing ≥ 6 bowel actions per day and 54% (IQR: 36–60%) reporting experiencing ≥ 2 bowel actions overnight.^{6,21,22} Defaecatory urgency, an inability to defer defaecation for more than 15 min, affected a majority (>50%) of patients in four included studies,^{6,22,32,44} whilst another two studies reported that approximately a third of patients experienced defaecatory urgency.^{4,21} Difficult stool evacuation was rare (<10%) in three studies,^{6,21,43} yet was reported as high as 85% by Khera *et al.*⁴⁴ although this was in a select population. An inability to differentiate between stool and flatus was reported by approximately 50% of patients post-IAPP according to five studies,^{6,32,43–45} yet Fazio *et al.* suggested this incidence was lower (20%).⁴

Despite the variability of bowel function in many included studies, overall patient satisfaction post-IAPP was very high. Four separate studies reported satisfaction rates greater than 90%,^{4,6,31,43} Lee *et al.* reported 83%³² satisfaction whilst Khera *et al.* satisfaction was lowest at 67%.⁴⁴ Ninety-two percent⁴³ and 93%³¹ of patients from two studies stated they would undergo IAPP again. Almost all patients from three studies were happy with the timing of surgery, with approximately 50% stating they would have had the surgery earlier if given the opportunity.^{46–48} Most patients (>75%) across five studies reported that having a pouch minimally impacted their social life^{4,6,21,43,49} whilst Wang *et al.* reported improved overall patient mental health post-IAPP.⁴⁹

Risk factors for complications

Thirty-one studies reported risk factors associated with various complications; most commonly pouch failure (16 studies) and

chronic pouchitis (10 studies). Risk factors were categorized into pre-operative, peri-operative, post-operative and patient demographic. Tables S5 and S6 contain all extracted data on risk factors associated with complications.

Twenty-three risk factors across 16 studies were significantly associated with pouch failure upon multivariate analysis. The most frequently documented were a final pathology of CD,^{4,11,27,50} peri-operative pelvic sepsis^{4,29,31} and anastomotic leak.^{17,30,34}

Fourteen risk factors across 10 studies were significantly associated with chronic pouchitis on multivariate analysis. The most frequently reported were pre-operative advanced disease/pancolitis,^{18,51} pre-operative steroid use^{31,51} and pre-operative extra-intestinal IBD manifestations.^{20,26}

Various surgical factors,^{7,17,30,31,34,50} pre-operative drug treatments,^{28,31,42,51} endoscopic findings,^{28,35} patient demographics and pre-operative haematological markers^{34,35,52} were also significantly associated with pouch failure and chronic pouchitis.

Discussion

This review illustrates high long-term complication rates post-IAPP in IBD patients. The need for drug treatment post-IAPP, including antibiotics, steroids and immunomodulators is common and most patients will require motility agents. Despite this, satisfaction rates post-IAPP are very high and pouch failure rates are low.

This review investigated the incidence and risk factors of chronic pouchitis. Our review found from 15 studies, a median incidence of chronic pouchitis of 17.1%. This is lower than a recent 2020 review by Pellino *et al.* which reported pouchitis affected a third of IAPP patients.⁸ Remarkably, Akiyama *et al.* recently reported a pouchitis rate of 80% in 2021.⁵³ Starkly different diagnostic criteria and ambiguous definitions for pouchitis likely contribute to this variability. The inclusion criteria for our review defined chronic pouchitis as >4 weeks of symptoms, as we believe this has the most clinical relevance. However, Akiyama *et al.*⁵³ (not included in this review) report pouchitis based to endoscopic findings rather than clinical symptoms. Furthermore, failure to delineate between acute and chronic pouchitis, seen in some studies,^{53–56} inflates overall pouchitis rates. These papers were excluded in this review, as we believe chronic pouchitis is of increased clinical significance, compared to single instances of acute pouchitis that respond to antibiotics.

Pouch neoplasm is another complication of interest given the potential mortality associated if undetected. Reassuringly, incidence rates are very low. Controversy surrounds the need for routine neoplasm surveillance in patients post-IAPP. In four included studies, the median incidence of pouch neoplasm was 1.765% (0.35–3.3%). Three of the four included studies^{10,36,37} recommended surveillance only be performed in symptomatic patients or those with previous colon neoplasia. Bobkiewicz *et al.*³⁶ reports all patients who developed pouch neoplasm had evidence of neoplasia in the colectomy specimen. Additionally, Derikx *et al.*¹⁰ associates prior dysplasia or colon cancer with a four and 25-fold increased risk respectively of pouch neoplasia. Therefore, despite being a concerning complication, pouch surveillance appears only necessary in at-risk or symptomatic patients post-IAPP.

Two outcomes of importance for pre-operative counselling are the need for ongoing medical therapy and quality of life post-IAPP. Many patients choose IAPP to control symptoms of medically refractory disease and reduce the need for long-term medication. This review highlights most patients post-IAPP will require some drug therapy for symptom control of pouch dysfunction or inflammation. This should be part of pre-operative consent to appropriately manage patient expectations. However, despite this, overall patient satisfaction is high post-IAPP (>90% in four out of six included studies). Impact on quality of life is difficult to measure due to the subjectivity of functional outcomes and different assessment tools utilized across included studies. Such outcomes should be investigated further in future prospective studies with standardized validated assessment tools.

Establishing pre-operative risk factors associated with IAPP complications allows clinicians to accurately inform patients prior to surgery, leading to better selection of surgical candidates and progression towards more personalized IBD care. Low haemoglobin (Sossenheimer *et al.*)³⁵ and albumin (Nisar and Sossenheimer *et al.*)^{34,35} pre-IAPP are significantly associated with pouch failure upon multivariate analysis. Similarly, pre-operative neutrophil-lymphocyte ratio is significantly associated with developing chronic pouchitis (Nishida *et al.*)⁵² Validating such associations with larger prospective studies is now required.

Surgical complications (pelvic sepsis^{4,14,25} and anastomotic leak^{17,30,34}) are most frequently associated with increased pouch failure rates. Thus, IAPP should be performed in high-volume tertiary centres with specialized pouch surgeons to prevent surgical complications and their sequela.

Excessive weight gain (>15%) post-IAPP is significantly associated with pouch failure,⁴² highlighting the importance of weight monitoring during post-operative follow-up. Other post-operative risk factors significantly associated with pouch failure and chronic pouchitis included biologic use,^{28,42} early pouchitis onset²³ and abnormal endoscopic findings.²⁸

There are several limitations to this review. All but one of the included studies are retrospective and heterogeneity across studies is high with respect to disease phenotype, underlying type of IBD, surgical indication (emergency vs. elective) and technique. Variable follow-up durations may result in 'ageing' pouches influencing results, whereby studies with long follow-up times have increased complication rates, as evidenced by Hashavia *et al.*¹⁸ and Beresneva *et al.*²⁷ where an increased incidence of chronic pouchitis and pouch failure were seen respectively. Additionally, all but five of the included studies were single centre cohorts which may also affect results and reproducibility.

Other limitations include a sole reviewer screened the included studies and quality assessment of studies is lacking, potentially increasing bias.

Advantages of this review are its comprehensive nature and robust methodology along with the large number of articles screened.

Prospectively maintained databases of patients undergoing IAPP and biobanking of serological and histological samples at the time of colectomy, with subsequent endoscopic assessments would greatly increase understanding in this field. Furthermore, prospective studies with clear diagnostic criteria for complications, the use

of validated quality of life assessment tools and standardized surgical techniques would aid our understanding of long-term pouch function and complications.

In conclusion, this review provides valuable and timely insight into long-term outcomes of IAPP in IBD patients. Whilst pouch complications are common, patient satisfaction post-IAPP remains very high. We have provided comprehensive insight into the risk of long-term complications and their risk factors. This will better inform clinicians and improve their ability to accurately counsel patients on the possible treatment outcomes allowing for patient empowerment, improved clinical decision making and more personalized care.

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Author contributions

Yusuf Hassan: Data curation; formal analysis; investigation; methodology; project administration; writing – original draft; writing – review and editing. **William Connell:** Writing – review and editing. **Alisha Rawal:** Data curation; visualization; writing – review and editing. **Emily K. Wright:** Conceptualization; supervision; visualization; writing – review and editing.

Conflict of interest

None declared.

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Supporting information

Additional Supporting Information may be found in the online version of this article at the publisher's web-site:

Table S1. Inclusion and Exclusion Criteria

Table S2. Incidence of Long-term IAPP Complications

Table S3. Incidence of Post-operative Medication Use

Table S4. Functional and Quality of Life Outcomes

Table S5. Collated Risk Factors for Complications

Table S6. Paper Breakdown of Complication Risk Factors