

Efficacy of Conventional Therapies for Perianal Fistulizing Disease in patients with Ileal Pouch Anal Anastomosis

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Introduction

- Restorative proctocolectomy with formation of an ileal pouch anal anastomosis (IPAA) has become the mainstay treatment in patients with medically refractory Ulcerative Colitis (UC)
- Many patients with UC will develop Crohn’s Disease (CD), predisposing them to development of a perianal or pouch associated fistula
- Despite excellent 20-year outcomes with pouch failure rates documented as low as 4%, up to 14% of patients will present with a fistula of the pouch [1]
- Several operations can be required to heal a perianal fistula, with only 52% healing after several operations, and 80% after pouch excision [2,3]
- Pouch- perianal and pouch- vaginal fistulas specifically present with significant associated morbidity and are associated with higher pouch failure rates, requiring a permanent ileostomy to resolve symptoms in up to 38% of patients [4].
- Current literature has examined the efficacy of individual procedures to treat rectovaginal and perianal fistulas, however, has yet to examine efficacy of several procedure classes specifically in patients with IPAA to specifically heal perianal or pouch associated fistulas.

Objectives

- Examine outcomes of conventional therapies for the treatment of perianal and rectovaginal fistulas in patients with a concomitant IPAA
- Identify perioperative risk factors associated with healing or recurrence of these fistulas in patients with IPAA.

Methodology

- **Design:** This is a retrospective study of patients greater than 18 years old who underwent an operation for perianal, rectovaginal, or pouch associated fistulas with a concomitant IPAA between 1995 and 2021 at the Cleveland Clinic Foundation.
- **Inclusion Criteria:** Patients 18 years or older at the time of the first operation to construct an IPAA and patients who have undergone surgical repair for a perianal or pouch associated fistula
- **Exclusion Criteria:** Patients whose fistula tract was not able to be identified at time of surgery, patient who only had insertion of a mushroom catheter or incision and drainage of a fistula related abscess at the time of operation, and patient who had only medical management of the fistula
- **Study Variables:** Patient demographics (age, sex, race), ASA status, stages of pouch surgery, preoperative imaging, medical management of disease, and post operative complications were collected for the primary IPAA surgery. IPAA outcomes such as pouch redo, pouch advancement, pouchitis, anastomotic leak, and pouch failure were recorded alongside perioperative parameters for these complications. Date of fistula surgery, class of fistula, preoperative imaging and medical management, and postoperative complications were recorded. Healing and recurrence of fistula and subsequent management were also recorded.

Methodology continued

- **Statistical Analyses:** Statistical analyses are currently pending. Univariate analysis will be used to identify single factors associated with healing (specific operation type, past medical history parameters, number of times in the operating room for the fistula, etc.). Multivariate logistic regression will be used to identify risk factors associated with fistula recurrence and healing. Subgroup analyses will evaluate pouch function and outcomes with fistula healing and recurrence.

Results

Results of statistical analyses are currently pending, however all data has been collected

Study Characteristics

- Nearly 450 patients were screened for eligibility
- After review, 221 patients were included after initial screening

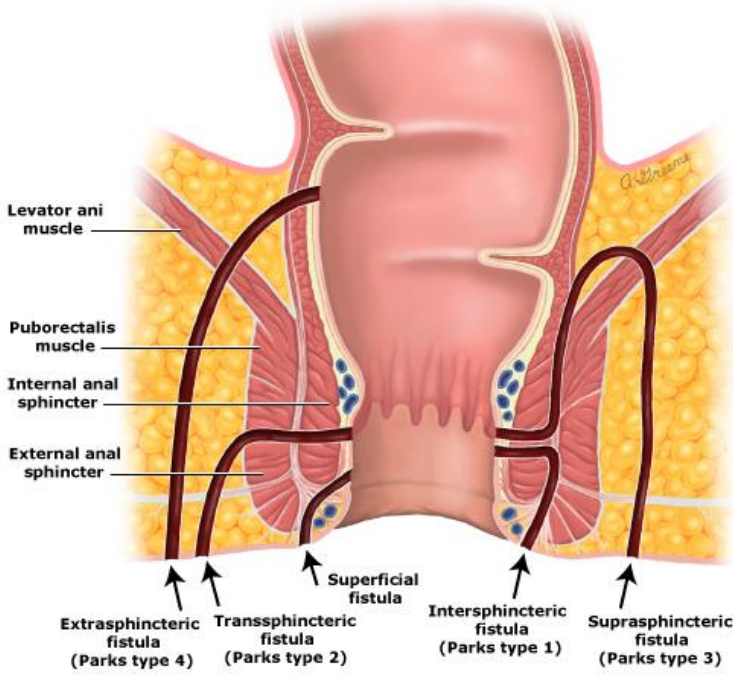
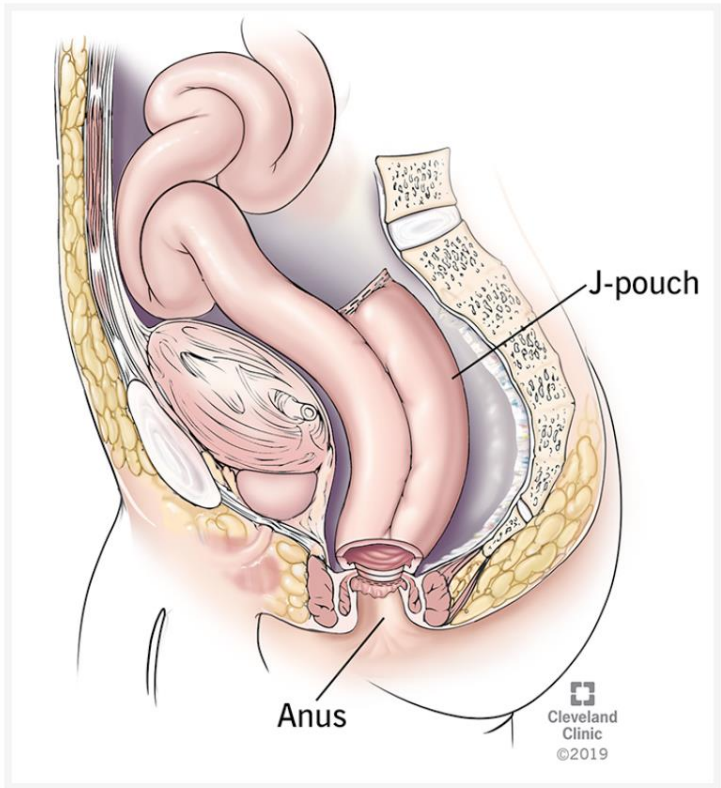


Figure 1 describes Park’s classification for distinguishing perianal fistula tract anatomy
Champagne BJ. Operative Management of Anorectal Fistulas. UpToDate. [Internet]. Waltham, Mass.: UpToDate; 2014. Available from: www.uptodate.com



Completed J-pouch procedure using two loops from the small intestine.

Figure 2 describes the anatomy of a completed J pouch IPAA

J-pouch surgery [Internet]. Cleveland Clinic. Cleveland Clinic Foundation; Available from: <https://my.clevelandclinic.org/health/treatments/21062-j-pouch-surgery>

Discussion

- **There is a lack of large-scale studies examining the efficacy of fistula therapy in patients with an IPAA, and fistula recurrence in relation to IPAA complications.**
- Phase I [5-8], II [9-11], and III [12] clinical trials using mesenchymal stem cells to heal perianal fistulas are ongoing
- Clinical trials have demonstrated promising efficacy in patients with Crohn’s disease associated perianal fistulas
- Provided the results of the present study, future clinical trials would be beneficial in studying the outcome of combined current surgical therapies with mesenchymal stem cells.

Conclusion

- This is an ongoing study. Pending statistical analyses will reveal efficacy of conventional fistula therapies in patients with an IPAA. Risk factors associated with both fistula recurrence and pouch failure will identify important parameters that can be used to best inform patients of their prognosis.

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