
Continuing Evolution of the Pelvic Pouch Procedure

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The results of the pelvic pouch procedure were reviewed to assess the surgical complication rate and outcome of patients who had the procedure performed with a stapled ileo-anal anastomosis with and without a defunctioning ileostomy. Between December 1982 and March 1992, 483 patients underwent a pelvic pouch (PP) procedure. Patients were divided into three groups: group I consisted of 325 patients (178 men and boys and 147 women and girls) who underwent a PP procedure with a handsewn ileo-anal anastomosis (IAA) with a defunctioning loop ileostomy. In group II, there were 87 patients (47 men and boys and 40 women and girls) who had a stapled IAA with a defunctioning ileostomy. Group III patients consisted of 71 patients (43 men and boys and 28 women and girls) who had a stapled IAA with no covering ileostomy. Assessment was made of the IAA leak rate, the surgical complications, the reoperation rate, and functional outcome. Early surgical complications included 40 (12%) IAA leaks in group I patients compared with only six (7%) leaks in group II patients who had a stapled IAA ($p < 0.05$). In group III patients, who had a stapled IAA but no covering ileostomy, there were 13 leaks (18%). Eleven of these 13 leaks healed spontaneously with tube drainage; one patient remains with a rectal tube in place 6 weeks after operation, and only one patient has required a reoperation (defunctioning ileostomy). Functionally, all patients with a healed IAA after a leak have had an excellent result comparable to those without a leak. Patients who were male, older than age 40, on steroids, and had had a true one-stage PP procedure, had a greater risk of developing an IAA leak. In two patients, there was intraoperative difficulty, and one of these patients had an IAA leak after operation. Disease activity at the resection margin and patient weight did not affect the leak rate. Our results suggest that the IAA leak rate is significantly reduced in patients with a stapled IAA with an ileostomy compared with those with a handsewn IAA. Omission of the defunctioning ileostomy is associated with a higher IAA leak rate, but sponta-

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neous healing occurs in almost all patients without impairment of functional results. In patients in whom the ileostomy is omitted, the IAA leak rate is greatest in male patients who have undergone a true one-stage PP procedure, are on steroids, and are older than age 40.

THE PELVIC POUCH procedure (PP) has become the procedure of choice at our center for most patients with ulcerative colitis and familial adenomatous polyposis requiring surgery. Although the morbidity rate after this operation is somewhat higher than a standard total proctocolectomy and conventional ileostomy,¹ it has the advantage of restoring gastrointestinal continuity and allowing patients to live a stoma-free existence.

In our own center, the procedure has evolved over the past decade. We have demonstrated that the results of leaving a short rectal cuff are as good or better than those with a long rectal cuff.² In addition, we also have demonstrated that the functional outcome of an "S" pouch properly constructed with a short outlet versus a "J" pouch are identical.³ There is still considerable debate, however, about the optimal level of the pouch anal anastomosis.^{4,5} Initially, all anorectal mucosa was stripped away and the anastomosis was performed at the dentate line. More recently, we have performed a stapled ileo-anal anastomosis (IAA), leaving 1 to 2 cm of anal transitional mucosa and columnar mucosa. Theoretic advantages of this modification include technical ease and perhaps more consistently improved functional results. Whether a stapled IAA leaving 1 to 2 cm of mucosa results in a better functional result is still controversial.⁵⁻⁷

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In our early series of patients, there was a 23% complication rate related to the loop ileostomy and its closure. In view of our large experience with the PP procedure and the high complication rate associated with loop ileostomy, we modified the PP procedure again by completing the IAA using a stapled technique and omitting the loop ileostomy.

This study was undertaken to compare the surgical complication rate and outcome of patients who had PP procedures with handsewn IAA with those who had a stapled IAA with or without a defunctioning ileostomy.

Patients and Methods

Patients

Between December 1982 and March 1992, 483 PP procedures have performed. The patients have been divided into the following study groups: group I, 325 patients with a handsewn IAA and a defunctioning ileostomy; group II, 87 patients with a stapled IAA and a defunctioning ileostomy; group III, 71 patients with a stapled IAA without a defunctioning ileostomy.

Patient Characteristics

Group I patients. Of the 325 patients, there were 170 males and 147 females with a mean age of 31.9 years (range, 14 to 69 years). Two hundred eighty-eight patients had ulcerative colitis, 21 had familial adenomatous polyposis, 15 had Crohn's disease, and one had indeterminate colitis. Two hundred twenty-one patients underwent an "S" pouch, 102 a "J" pouch, and two a "W" pouch. One hundred sixty patients had a previous subtotal colectomy before their pelvic pouch and defunctioning ileostomy. One hundred forty-four patients had no previous colon surgery, and 21 had other procedures related to their colon.

Group II patients. There were 87 patients, of whom 47 were men and boys and 40 were women and girls, with a mean age of 31.5 years (range, 17 to 52 years). Eighty patients had ulcerative colitis, two had familial adenomatous polyposis, two had Crohn's disease, and three had indeterminate colitis. Eighty-five patients had a "J" pouch and two had an "S" pouch. Forty-five patients had no previous surgery, and 41 had a previous subtotal colectomy and one had a previous left hemicolectomy.

Group III patients. In group III, there were 71 patients, of whom 43 were men and boys and 28 were women and girls. The mean age was 33 years (range, 14 to 52 years). Sixty-nine patients had ulcerative colitis; one, familial polyposis; and one, indeterminate colitis. Seventy had a "J" pouch and one had an "S" pouch. Sixty-nine patients had the IAA performed using the double-staple technique. In two, a purse string suture was inserted into the distal

rectum. Forty-nine patients had a previous subtotal colectomy, and 21 had no previous surgery and were considered to have had a true one-stage PP procedure. One patient had had a previous sigmoid colectomy.

All patients were followed prospectively with data collected and stored on a computerized database.

Operative Technique and Postoperative Management

All group I patients had a mucosectomy and a handsewn IAA of either the "J" or "S" pouch to the dentate line using 2-0 vicryl suture material. In the group II patients, the rectal dissection was carried down to the level of the levator ani muscles. The ileopouch anal anastomosis was completed using the double-stapling technique or by inserting a purse string suture in the rectal cuff and performing an end-to-end anastomosis with a circular stapler. In all group I and II patients, a defunctioning ileostomy was used. In group III patients, the pouch construction, rectal dissection, and ileopouch anal anastomosis were performed in a similar manner. No defunctioning loop ileostomy was used in any patient, however. Instead, all patients were defunctioned with the placement of a 30-French Foley catheter used as a rectal tube inserted into the pouch. The rectal tube remained in place for 5 to 8 days after operation or until normal gastrointestinal function returned. Pouchograms were not performed routinely before removal of the rectal tube.

Outcome Measures

The primary outcome measure was the development of an IAA leak. All leaks were identified by clinical parameters such as the presence of pelvic pain, lower abdominal pain, postoperative fever, leukocytosis with confirmation of the leak by contrast studies. Other outcome measures included surgical complications, the reoperation rate and the functional outcome. The factors that were analyzed for their association with an IAA leak included age, sex, steroid usage, weight, intraoperative difficulty, anastomotic stapling technique, severity of disease at the distal margin, and whether the patient had had a subtotal colectomy previously.

Statistical Analysis

All data are presented as means \pm standard deviation. Differences were tested using the z statistic.

Results

There were no perioperative deaths. The mean length of follow-up, as shown in Table 2, varied because modifications were introduced at different times.

Early Surgical Complications

The IAA leak rate in each group is shown in Table 1. In group I patients, with a handsewn IAA, there were 40 leaks (12% of patients). This compared with only six in 87 (7%) patients in group II ($p < 0.05$). In group III patients, who had a stapled IAA without a defunctioning ileostomy, there were 13 leaks (18% of 71 patients). The IAA leak rate was statistically significantly higher in group III patients than in group II patients.

There were an equal number of pouch leaks in the three groups (Table 1), and there was a slight, but not statistically significant, increase in intra-abdominal sepsis in group III patients.

Outcome of Patients With IAA Leaks

Of the 46 patients who developed IAA leaks in group I and group II, 38 required at least one operative intervention (mean, 2.2 procedures/patient) in an attempt to repair and salvage their pouches (Table 2). The procedures included local anal repairs, fistulotomies, debridement, and local suture with counterdrainage, and advancement flap techniques, but did not include re-establishment of an ileostomy or removal of the pouch.

There were no local operative ileoanal reparative procedures performed in group III patients. These patients were treated with intravenous antibiotics, and by maintaining the pouch on straight drainage with a 30-French rectal tube. Once stabilized, they were discharged from hospital with the tube in place and were seen at regular intervals until there was radiologic evidence of complete healing. After confirmation of healing, the rectal tube was removed. In 11 of 13 patients (85%), the leaks healed spontaneously, compared with 4 of 46 patients (9%) with leaks in groups I and II ($p < 0.05$). Another patient in group III is well, but the leak has not fully healed 6 weeks after operation.

Sixteen (40%) of 40 patients who developed an IAA leak in group I eventually had their pouches removed, and three (7.5%) had an ileostomy re-established. One (16.7%) of the six patients in group II required pouch removal and two (33.3%) required re-establishment of the ileostomy. Conversely, in group III patients, despite the fact that there was an 18% IAA leak rate, only one (7.7%)

TABLE 1. *Early Surgical Complications*

	Group I (n = 325)	Group II (n = 87)	Group III (n = 71)
IAA leaks*	40 (12%)	6 (7%)	13 (18%)
Pouch leaks	8 (2%)	2 (2%)	3 (4%)
Intra-abdominal sepsis	9 (3%)	3 (4%)	6 (8%)

* Group I vs. Group II, $p < 0.05$; Group II vs. Group III, $p < 0.05$.

TABLE 2. *Outcome of Patients With IAA Leaks*

	Group I (n = 325)	Group II (n = 87)	Group III (n = 71)
No. of IAA leaks	40	6	13
Mean follow-up (yr)	4.9	2.0	0.4
Total no. of patients with reoperations	35	3	1
Ileostomy reestablished	3 (7.5%)	2 (33.3%)	1 (7.7%)
Pouch removed	16 (40%)	1 (16.7%)	0 (0%)

patient required construction of an ileostomy because of intra-abdominal sepsis.

Functional Outcome of Group III Patients With IAA Leaks

Of the 11 patients in group III who have had complete healing of the IAA leak, all are fully continent. There is no urgency in any of these patients. Three of the 11 take Imodium (Janssen Pharmaceuticals, Piscataway, NJ) on an intermittent basis. None have a strictured IAA. The mean number of bowel movements in this group is five per 24 hours, with a range of three to eight.

Factors Affecting the IAA Leak Rate in Group III Patients

As seen in Table 3, of the eight factors analyzed, four had a statistically significant association with IAA leak: single-stage *versus* previous subtotal colectomy; the use of steroids; age; and sex. In this univariate analysis, seven IAA leaks occurred in 22 (32%) patients who had a true one-stage procedure, compared with six in 49 (12%) patients who had had a previous subtotal colectomy ($p < 0.05$). Fifteen patients were on a dose of 15 to 60 mg prednisone before their operations. Five (33%) developed a leak compared with eight of 56 (14%) who were not on steroids ($p < 0.05$). In addition, there was a significantly higher leak rate in male patients compared with women and girls (34% *versus* 13%) and patients older than age 40 compared with those younger than age 40 (35% *versus* 13%) ($p < 0.05$).

There were only two patients in whom there was some intraoperative difficulty in the form of tension at the IAA.

TABLE 3. *Factors Affecting IAA Leak Rate in Group III Patients*

Factor	No. of Patients	No. of Leaks (%)
Single stage*	22	7 (32%)
Previous STC	49	6 (12%)
Steroids (15–60 mg)*	15	5 (33%)
No steroids	56	8 (14%)
<40 yr*	54	7 (13%)
>40 yr	17	6 (35%)
Male*	43	10 (23%)
Female	28	3 (11%)

* $p < 0.05$.

One of these patients developed an IAA leak. There was severe disease activity at the distal resection margin in six of the 71 patients. None of these six patients developed an IAA leak. The disease severity in the remaining 65 patients was described as "moderate" or "mild." There was no dysplasia found in any of the distal resection margin specimens. There was also no difference in the IAA leak rate between those individuals who were above average weight *versus* those who were average or below average weight.

Discussion

Although the PP procedure remains our operation of choice for most patients with ulcerative colitis, there is a significant morbidity rate.¹ In our attempts to improve both the technical results and functional outcome, we have continued to make modifications to the technique. In our initial series of patients (group I), all had a complete mucosectomy with a handsewn IAA and defunctioning loop ileostomy. Anal manometric results, however, suggested that there may be damage to the internal sphincter due to excessive stretching during the rectal mucosectomy, and that this might lead to poor functional results.⁶ Heald and Allen,⁴ as well as Johnston et al.,⁶ reported improved functional results in two separate series of patients in whom there was preservation of the anal canal transitional zone. A stapled circular type of anastomosis was performed between the pouch ("J" pouch) or the outlet ("S" pouch) and the upper anal canal, leaving approximately 1 to 2 cm of mucosa above the dentate line. Lavery et al.,⁸ in a small series of patients from the Cleveland Clinic, demonstrated manometric evidence of improved resting pressures and clinical evidence of reduced nocturnal soiling in patients with a stapled anal anastomosis when compared with patients undergoing a conventional mucosectomy. Conversely, there was no difference in the functional results in patients randomized to a handsewn IAA with a mucosectomy or a stapled IAA without mucosectomy in a randomized controlled trial reported by investigators at St. Mark's Hospital.⁹ An additional study reported by Williams et al.⁵ reached the same conclusions. Although this subject is controversial, initial results suggest that function seems to improve more quickly with respect to continence and nocturnal soiling in those patients in whom a mucosectomy is not performed.^{5,6} In addition, operative time is reduced.

There does, however, remain the theoretical disadvantage of the development of continuing disease in the remaining anal mucosa as well as the risk of malignancy. Although most surgeons would agree that this small amount of mucosa is unlikely to result in any significant inflammation and thus clinical symptoms, the issue of

the cancer risk subsequently developing in this segment is important. It is nearly impossible to estimate the risk of cancer in the 1 to 2 cm of retained anorectal mucosa, partly because the exact risk of colorectal cancer developing in patients with chronic ulcerative colitis remains controversial. It is rare, however, to find carcinomas located in the anal canal in those patients with long-standing ulcerative colitis. Nevertheless, the risk of development of carcinoma in this short segment is theoretically greater than with a complete mucosectomy, even though there is still a risk of carcinoma developing in patients who do undergo a complete mucosectomy, as it is difficult to be certain that all of the diseased mucosa has been removed. To date, there have been at least two reported cases of cancer developing in the rectal cuff of patients who had previously undergone an ileo-anal pouch procedure with mucosectomy.^{10,11} In addition to this, King et al.¹² reported on four of 16 patients that they studied who had moderate dysplasia in the anal canal stripping as well as one patient who actually had a carcinoma. Tsunoda et al.¹³ reported that there was severe dysplasia found in the anorectal mucosa in three of 12 patients in whom severe dysplasia was found in the resected specimen. Therefore, it would seem appropriate to do a complete mucosectomy in those patients in whom the indication for surgery was dysplasia and in particular in those patients who have dysplasia in the rectum.

In our series, there was a statistically significant decrease in the IAA leak rate in those patients who had had a stapled IAA with a defunctioning ileostomy compared with those who had had a conventionally performed handsewn IAA with a defunctioning ileostomy. The reoperation rate in the stapled group was also decreased, as was the failure rate and pouch removal rate. The latter may be due to our experience in the management of these complications and our ability to salvage the pelvic pouch, rather than due to the difference in the technique.

The incidence of anastomotic disruption with local sepsis after performing the PP procedure conventionally, with a defunctioning ileostomy, ranges from 5% to 15% in larger reported series.¹⁴ In addition, there are complications related to the loop ileostomy and its closure. In our current series, stomal complications occurred in 5%, small bowel obstruction in 21%, high ileostomy output in 33%, and, anastomotic leak from the ileostomy closure site in 2.5% of patients. In addition, IAA leaks can become evident after closure of an ileostomy, necessitating yet another operation. In other series, between 3% and 7.4% of patients developed peritonitis after closure of the loop ileostomy.^{15,16} Mattikainen¹⁷ recently reported that 50% of their patients with covering ileostomies had stomal difficulties. Becker and Raymond¹⁸ reported that complications occurred in 25% of 100 patients who underwent ileostomy closure after ileal pouch anal anastomoses.

The current controversy regarding whether an ileostomy should be performed involves weighing the risk and morbidity of developing an IAA leak against the morbidity, and increased hospitalization associated with loop ileostomy and its subsequent closure.

The PP procedure without an ileostomy has been attempted by some surgeons in the past.¹⁹ The University of Minnesota group reported performing a PP procedure without a covering loop ileostomy in six patients. Five of these patients developed septic complications. Other results of single-stage PP procedures have reported failures in the range of 10% to 33%.²⁰⁻²² More recently, however, eight of nine selected patients in the Mayo Clinic series had successful results,²³ and Peck reported a series of 38 patients, 34 of whom had primary healing of their anastomosis.²⁴ In the remaining four patients, minimal anastomotic separation occurred and healed spontaneously by secondary intention without further surgery. Mattikainen et al.¹⁷ reported only one failure in 25 consecutive patients done as a single-stage procedure. Jarvinen²⁵ reported that there was no difference in terms of complications between those patients who did or did not have a covering loop ileostomy. He reported also that there was a significant saving in total hospital stay and in operating time in patients who did not have a covering ileostomy. Launer and Sackier²⁶ also reported no anal anastomotic leaks in a small series of eight patients in whom an intraluminal bypass tube was used in conjunction with a stapled pouch-anal anastomosis.

In our own series, there was a significantly higher anal anastomotic leak rate in those patients without a covering loop ileostomy. Only one of these patients, however, required reoperation in the form of a defunctioning ileostomy. Eleven of the 13 patients have healed their leaks spontaneously with tube drainage and antibiotic therapy. None of the procedures have been considered failures, because none of the pouches have been removed. This contrasts quite sharply to the almost 5% of patients who required removal of their pouch because of IAA leaks in our initial 325 patients. It has also been our experience that the IAA leaks have healed spontaneously in these patients, whereas in the patients that have had a PP procedure with a covering ileostomy, spontaneous healing after an IAA leak has occurred infrequently. This might be due to the fact that there is less tension at the IAA. When constructing a loop ileostomy, there is often considerable tension placed on the mesentery of the loop of small bowel that is being exteriorized. This is the same mesentery that extends down to the pouch-anal anastomotic site and therefore may impair the ability to heal that anastomosis spontaneously if a leak occurs.

The functional outcome of patients who did develop an IAA leak without a covering ileostomy has been excellent. Although the follow-up has been short, all patients

who have healed their anastomosis are fully continent, none have urgency, and there are no strictures that have developed. Only three are on anti-diarrheal medication, and the frequency of stool evacuation per 24 hours has been comparable to our other patients who have had stapled IAAs without a leak.

Patients in group III were selected but did represent approximately 90% of patients who underwent a PP procedure during this time. In the others, for various reasons, the attending surgeon believed it necessary to perform a defunctioning ileostomy. Approximately two thirds of the patients in group III, however, had had a previous subtotal colectomy, compared with fewer than half in the other two groups. Again, this reflects the selection of patients who were most suitable for the procedure without an ileostomy. In this review, we have attempted to further determine which patients are most suitable for having the procedure performed without a covering ileostomy. It is clear that patients who have not had a colectomy previously and are currently on steroids are at considerable risk for developing an IAA leak when the anastomosis is not protected with a loop ileostomy. This likely represents the difficulties in operating on sicker nutritionally depleted patients with active disease who are on steroid medication. We also attempted to correlate the disease severity at the distal margin of the specimen with the IAA leak rate, but there was no positive correlation with severity of disease, and in fact, none of the six patients who had severe disease at the margin developed an IAA leak. Male patients also had a higher leak rate, probably because they tend to be more difficult to operate on than female patients.

In summary, in our own series, the IAA leak rate is significantly reduced in patients with a stapled IAA with a defunctioning ileostomy compared with those with a handsewn IAA and a defunctioning ileostomy. The omission of the defunctioning ileostomy is associated with a higher IAA leak rate, but spontaneous healing occurs in almost all patients, and the functional outcome is not adversely affected. In addition, our results suggest that the rate of IAA leakage is greatest in men, patients who undergo true one-stage procedures, are on steroids, and are older than age 40.

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DISCUSSION

DR. HARVEY J. SUGERMAN (Richmond, Virginia): I would like to thank the authors for corroborating our previous series of stapled ileoanal procedures without a temporary ileostomy, published last year. (Sugerman HJ, Newsome HH, DeCosta G, Zfass AM. Stapled ileoanal anastomosis for ulcerative colitis and familial polyposis without a temporary diverting ileostomy. *Ann Surg* 1991; 213:606-619.) We have extended our experience to 55 stapled ileoanal anastomoses, of whom 49 had the operation without a primary ileostomy. Of these, 37 were taking high-dose prednisone and 15 had the procedure undertaken for semi-emergent or emergent conditions, such as severe, intractable bloody diarrhea and toxic colitis without colonic dilatation. This latter group had the highest incidence of complications, necessitating three subsequent ileostomies, which has led us to become less aggressive in this subset of patients. There was one pelvic abscess and one pouch leak in the patients who were not taking prednisone, both of whom were successfully drained without an ileostomy and have subsequently done well.

We have changed our technique in several respects from our previous publication. We currently use a standard disposable auto-suture TA-30 stapler with 3.5-mm staples rather than the Roticulator TA-30, because it is 1.5 cm less wide, permitting rectal transection closer to the levator sling and dentate line. Our average distance between the anastomosis and the dentate line has decreased significantly from 1.8 to 0.7 cm, and we have been at the dentate line in six patients from above with excellent stool continence in five of these six patients day and night. Stool control has been clearly much better with the stapled procedure in our experience, as well as in that of others.

We have had an occasional problem with disruption of the TA-30 staple line on insertion of the Premium CEEA stapler from below. Two superimposed TA-30 staple lines have appeared to prevent this problem. Should a staple line disruption occur, one can insert two perpendicular Gelpi retractors as in a standard mucosal stripping procedure and hand-sew the disrupted anal canal from below. I have several questions for Dr. Cohen.

One, have you performed total colectomy, proctectomy, and stapled ileoanal procedures in patients on high-dose steroids or immunosuppressive agents, such as 6-MP, with intractable bleeding or toxic colitis, with or without colonic dilatation, or do you do a subtotal colectomy, ileostomy, and return at a later time for the proctectomy and ileoanal procedure? I notice that many of your patients had subtotal colectomies, and it is my understanding that many of these patients have been referred to you with that procedure. We now believe that the entire procedure can be performed in most patients at the primary operation, but that most of these patients should now have a temporary diverting ileostomy.

Two, do you use the Roticulator TA-30 stapler?

Three, how much residual tissue are you leaving between the dentate line and the ileoanal anastomosis? We have had five of six patients with excellent stool control when the stapled anastomosis was at the dentate line. In view of this, do you still believe, as does the Cincinnati group, that the improved continence is due to preservation of the transition zone, or is it secondary to less manipulation with possible damage to the proprioceptive nerve fibers of the anal canal?

Have you had any TA-30 staple line disruptions on insertion of the Premium CEEA stapler? And if so, how do you address this problem?

And lastly, our study has documented, as have other studies, an improved continence rate with the stapled technique. Have you noted a similar improvement?

Our data support the authors' hypothesis that the stapled procedure is a safer, more secure anastomosis that can be performed in most instances without a temporary diverting ileostomy, avoiding the need for a second operative procedure with its complications and expense.

DR. MALCOLM C. VEIDENHEIMER (Burlington, Massachusetts): Of our 500-odd ileal pouch anal anastomoses, 3.5% have failed, and 60% of the failures have been in people with Crohn's disease or indeterminate colitis. The main source of failure is sepsis in the pelvis.

It is true that the operation that goes easiest for the surgeon usually goes easiest for the patient. But I rise to bring some constraint to the