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Ileal Pouch-anal Anastomosis Complications and Pouch Failure

A systematic review and meta-analysis

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Objective: This systematic review aims to assess the incidence of pouch failure and the correlation between ileal pouch-anal anastomosis (IPAA)-related complications and pouch failure.
Background: Previous studies demonstrated wide variation in postoperative complication rates following IPAA.
Methods: A systematic review was performed by searching the MEDLINE, EMBASE, and Cochrane Library databases for studies reporting on pouch failure published from January 1, 2010, to May 6, 2020. A meta-analysis was performed using a random-effects model, and the relationship between pouch-related complications and pouch failure was assessed using Spearman's correlations.
Results: Thirty studies comprising 22,978 patients were included. Included studies contained heterogenic patient populations, different procedural stages, varying definitions for IPAA-related complications, and different follow-up periods. The pooled pouch failure rate was 7.7% (95% confidence intervals: 5.56–10.59) and 10.3% (95% confidence intervals: 7.24–14.30) for studies with a median follow-up of ≥5 and ≥10 years, respectively. Observed IPAA-related complications were anastomotic leakage (1–17%), pelvic sepsis (2–18%), fistula (1–30%), stricture (1–34%), pouchitis (11–61%), and Crohn's disease of the pouch (0–18%). Pelvic sepsis ($r=0.51$, $P<0.05$) and fistula ($r=0.63$, $P<0.01$) were correlated with pouch failure. A sensitivity analysis including studies with a median follow-up of ≥5 years indicated that only fistula was significantly correlated with pouch failure ($r=0.77$, $P<0.01$).
Conclusions: The single long-term determinant of pouch failure was pouch fistula, which is a manifestation of a chronic leak. Therefore, all effort should be taken to prevent an acute leak from becoming a chronic leak by early diagnosis and proactive management of the leak.

Keywords: ileal pouch-anal anastomosis, ulcerative colitis, pouch failure

The ileal pouch-anal anastomosis (IPAA), introduced in 1978 by Parks and Nicholls,[1] has evolved as the gold standard to restore intestinal continuity in patients with ulcerative colitis (UC), familial adenomatous polyposis (FAP), and in selected patients with Crohn's disease (CD) after proctocolectomy. Although IPAA is associated with low mortality[2] and good patient satisfaction,[3] long-term pouch failure occurs in 5–15% of cases.[4] Various IPAA-related complications (ie, anastomotic leakage, pelvic sepsis, fistula, stricture, pouchitis, CD of the pouch) are associated with pouch failure, of which pelvic sepsis appears to be the most important risk factor.[5–8] To reduce the risk of pelvic sepsis, the focus has been on optimization of preoperative performance status, staged procedures,[9–11] minimally invasive techniques,[12] diversion of the pouch,[13] and adequate postoperative management[14] (ie, early detection and active treatment of anastomotic leaks). The optimal timing of IPAA creation after colectomy[9–11] and the role of routine fecal diversion to reduce pelvic sepsis[13,15,16] are still debated topics.

A large number of observational studies, mostly from specialized centers, have reported postoperative outcomes following IPAA surgery.[16–24] The rate of IPAA-related complications varies widely in the literature and may have increased in the era of biologics.[25] However, ambiguous definitions for anastomotic complications, differences in postoperative assessment, and duration of follow-up make a comparison of outcomes following IPAA challenging. To improve the current understanding of outcomes following IPAA, this systematic review aimed to compile the literature to date and determine the incidence of pouch failure and pouch-related complications. In addition, we examined the correlation between pouch-related complications and pouch failure.

METHODS

This systematic review and meta-analysis were performed in accordance with the Preferred Reporting Items for Systematic Reviews and Meta-Analysis (PRISMA)[26] statement and the Meta-analysis of Observational Studies in Epidemiology (MOOSE) guidelines.[27] This review has been registered on the PROSPERO Registry [ID=CRD42020221518].

Eligibility Criteria

Retrospective and prospective observational studies containing original data on pouch failure after primary IPAA in

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patients aged ≥18 years were included. Studies published from 2010 onwards were selected for the current meta-analysis, as studies published between 2000 and 2009 were included in a previous meta-analysis.[2] Studies, including patients with UC only or UC and a combination of patients with CD, indeterminate colitis, FAP, and colorectal cancer, were eligible. Studies in which pouch failure was solely defined as pouch excision were excluded. Studies with a small sample size (<100 patients) and therefore potentially carrying an increased risk of sampling bias were excluded. Studies without a retrievable full text (ie, abstracts, nonpublished data) or English version were also excluded. To avoid repeated use of data from 1 patient due to multiple publications from the same institution, only the most recent or largest series per institution was included.

Literature Search Strategy

A comprehensive database search was performed using the MEDLINE (PubMed), EMBASE (Ovid), and Cochrane Library databases, focusing on studies evaluating pouch failure following IPAA published between January 1, 2010, and May 6, 2020. The search contained both MeSH and free-text terms and was composed in consultation with a clinical librarian (FE). The following search terms were used: ("restorative proctocolectomy," "ileal pouch anal anastomosis," "IPAA," "ileal pouch") AND ("postoperative complications," "anastomotic leak," "anastomotic complication," "pelvic sepsis," "pouch failure," "pouch function," "pouch fistula," "long term outcome," "long term complication"). Reference mining of the included studies was conducted to find any additional articles. The full literature search is shown in Table, Supplemental Digital Content 1, http://links.lww.com/AOSO/A42.

Study Selection

Study selection was performed in 3 phases according to the PRISMA statement (Figure, Supplemental Digital Content 1, http://links.lww.com/AOSO/A41). All identified studies were independently screened based on their title and abstract by 2 reviewers (L.H. and K.W.) using Rayan online software.[28] Subsequently, the 2 independent researchers (L.H. and K.W.) screened the full texts and selected studies for inclusion in the systematic review and meta-analysis. Any discrepancies between the researches were resolved through a joint discussion that included a third researcher (W.B.).

Data Collection

Data collection included study characteristics (author, publication year, study design, inclusion period, number of included patients, country, follow-up time), patient characteristics (age, gender, diagnosis), surgical characteristics (number of stages of IPAA, percentage of diverted pouches), and postoperative outcome (pouch failure, anastomotic leak, pelvic sepsis, pouch-related fistula, stricture, CD after IPAA creation, pouchitis). A one-stage procedure was defined as a proctocolectomy with IPAA creation. In a 2-stage procedure, the proctocolectomy with IPAA creation and defunctioning ileostomy was followed by reversal at the second stage. A modified 2-stage was defined as a subtotal colectomy with defunctioning ileostomy, followed by completion proctectomy with IPAA and ileostomy reversal at the second stage. In a 3-stage procedure, a subtotal colectomy with end ileostomy was performed, followed by completion proctectomy with IPAA and defunctioning ileostomy, and ileostomy reversal at the third stage. Data and definitions of postoperative outcomes were extracted from included published reports. Study authors were not contacted for additional data.

Risk of Bias Assessment

The risk of bias was assessed by 2 independent researchers (L.H. and K.W.) using the Joanna Briggs Institute (JBI) checklist for case series.[29] The predefined criteria for each of the 10 questions in the JBI checklist to assign low, unclear or high risk of bias are presented in Table, Supplemental Digital Content 2, http://links.lww.com/AOSO/A42. The risk of bias across studies was assessed and included the risk of publication, detection, and reporting bias.

Statistical Analysis

Categorical data are presented as numbers and percentages, and continuous data are presented as mean and SD or median and interquartile range as appropriate according to the variable's distribution. Postoperative complications were pooled. The meta-analysis was performed by inverse variance weighting with a random-effects model in the "meta" package using R statistical software (R Development Core Team, version 3.6.1).[30] Results were presented in forest plots giving an estimate of the mean proportion with a 95% confidence interval (CI). We assessed heterogeneity using I^2, where $I^2 \geq 50\%$ was considered to represent significant heterogeneity and resulted in the use of a random effect model. For pouch failure, a sensitivity analysis was performed including only studies with a median follow-up of ≥5 and ≥10 years. A Spearman's correlation between pouch-related complications and pouch failure was performed using IBM SPSS statistics for Windows version 26 (IBM Corp., Armong, NY). A sensitivity analysis was performed to identify factors correlated with long-term pouch failure in studies with a median follow-up of ≥5 years. A 2-sided *P* value of less than 0.05 was considered statistically significant.

RESULTS

Search Results

A total of 1947 studies were identified through the database search: 803 studies via PubMed, 1064 via EMBASE, and 80 via the Cochrane Library. After removal of duplicates, 1330 records were screened for eligibility based on their title and abstract. This resulted in the screening of 191 full-text articles and the inclusion of 30 studies (Table 1). Hand screening of reference lists yielded no additional articles eligible for inclusion. The PRISMA study selection flow chart is shown in Figure, Supplemental Digital Content 1, http://links.lww.com/AOSO/A41.

Study Characteristics

This systematic review includes 30 studies with a total of 22,978 patients, consisting of 20,839 patients with UC, 524 with indeterminate colitis, 101 with CD, 516 with FAP, and 1023 with other or unspecified diagnosis. Six of the 30 studies were multicenter studies. Three studies originated from Asian countries, whereas 27 studies originated from Western countries. The majority of studies (19/30) had a median follow-up of at least 5 years and 4 studies did not report the follow-up time (Table 1).

Surgical Characteristics

A laparoscopic approach was used in 24% of cases, which was reported in 13 studies. Nineteen studies reported on whether a 1-, 2-, modified 2-, or 3-stage approach was used. The majority of pouches were done using a 2-stage approach (42.2%), while 19.7% used a 1-stage approach, 9.0% used a modified 2-stage, and 29.1% used a 3-stage approach (Table, Supplemental Digital Content 3, http://links.lww.com/AOSO/A42). In total, 83.7% of the pouches were primary diverted (range of 23.3–100%),

TABLE 1.

Study and Patient Characteristics of 30 Included Studies Reporting on Pouch Failure Following Primary IPAA Published Since 2010

Author	Year	Country	Study Period	Study Type	N	Disease UC/IC/CD/FAP/ Other or Unspecified	Age	Gender (% Female)	Laparoscopic Approach (%)	Stapled Anastomosis (%)	Primary Diverting Ileostomy (%)	Median Follow-up Time (yrs)
Carcamo et al[31]	2020	Chile	1984–2017	R, single center	116	116	35	67 (57.8)	11 (9.48)	–	116 (100)	20
Cataneo et al[32]	2019	USA	2004–2017	R, single center	176	–	–	–	79 (44.9)	–	176 (100)	–
Dafnis[33]	2016	Sweden	1993–2012	R, single center	124	112/0/11/0/1	44	53 (42.7)	–	115 (92.7)	123 (99.2)	11.2
Die et al[34]	2020	Spain	1983–2015	R, single center	139	139	–	60 (43.2)	–	85 (61.2)	108 (77.7)	12 *
Feinberg et al[20]	2020	USA	1986–2016	R, single center	3468	3300/168/0/0/0	39	1512 (43.6)	–	–	3143 (90.7)	7.9
Hashimoto et al[35]	2013	Japan	2000–2012	R, single center	119	119	35/39	42 (38.2) n = 110	33 (30.0)	67 (60.9)	–	5.5
Helavirta et al[36]	2016	Finland	1985–2009	R, single center	352	352	36	149 (42.3)	–	69 (19.6)	133 (37.8)	5
Ikeuchi et al[37]	2010	Japan	1983–2007	R, single center	944	944	–	–	1 (0.1)	21 (2.2)	686 (72.6)	–
Karjalainen et al[23,38]	2019	Finland	2005–2016	R, single center	510	510	39	198 (38.8)	0 (0.0)	52 (10.2)	119 (23.3)	6.9
Karlbom et al[39]	2011	Sweden	1985–1996	R, single center	188	188	32	72 (38.3)	–	–	154 (81.9)	12.5
Kayal et al[40]	2019	USA	2008–2017	R, single center	386	363/23	37	140 (46.6)	281 (72.8)	275 (71.2)	311 (80.6)	2
Landerholm et al[18]	2017	Sweden	1964–2010	R, population based	1720	1720	36.8	643 (37.4)	–	–	–	12.6
Lee et al[41]	2019	USA	2000–2015	R, single center	212	212	36	87 (41.0)	45 (21.2)	212 (100)	212 (100)	4.7*
Leowardi et al[42]	2010	Germany	1988–1996	R, single center	294	294	33	133 (45.2)	–	0 (0)	294 (100)	11.5
Lightner et al[19] Farouk et al[43]	2017	USA	1981–2015	R, single center	1875	1875	34	855 (45.4)	–	–	1855 (98.4)	–
Lorenzo et al[44]	2016	Italy	1985–2014	R, single center	185	185	33	61 (33.0)	–	128 (69.1)	128 (69.2)	11.3
Mark-Christensen et al[22,45]	2017	Denmark	1980–2013	R, population based	1991	1991	33	954 (47.8)	165 (8.3)	–	1849 (92.9)	11.4
McCombie et al[46]	2016	New Zealand	1984–2013	R, population based	136	104/4/15/12/1	39	61 (44.9)	–	–	–	12
Mege et al[10]	2016	France	2000–2015	R, single center	185	164/1/20/0/0	39/43	78 (42.2)	185 (100)	180 (97.3)	185 (100)	3
Mennigen et al[47]	2011	Germany	1997–2009	R, single center	122	122	34/38	44 (36.1)	–	71 (58.2)	89 (73.0)	3.3
Rokke et al[48]	2011	Norway	1988–2002	R, single center	134	134	43	57 (42.5)	–	134 (100)	54 (43.9)	11
Sahami et al[16]	2016	NL, Belgium, USA	1990–2014	R, multicenter	621	545/59/17/0/0	38	270 (43.6)	289 (46.5)	601 (96.8)	305 (49.1)	3.3
Sampietro et al[49]	2018	Italy	2007–2016	R, single center	150	143/3/4/0/0	43/51	58 (38.6)	150 (100)	143 (95.3)	138 (92.0)	5.1
Tan et al[50]	2014	Australië	1999–2011	R, single center	142	142	43	60 (42.3)	–	141 (99.3)	142 (100)	3
Uchino et al[24]	2017	Japan	2005–2014	R, multicenter	2376	2376	40	963 (40.5)	–	1078 (45.4)	1664 (70.0)	6.7
Wasmuth et al[51,52]	2010	Norway	1984–2007	R, single center	315	287/7/5/11/5	32/36	119 (37.8)	–	187 (59.4)	256 (84.2)	13.3
Wibmer et al[53]	2010	Germany	1997–2008	R, single center	185	141/0/0/44/0	37	79 (42.7)	66 (35.7)	0 (0)	163 (88.1)	3.9*
Worley et al[21]	2017	UK, Belgium, Denmark, NL, Spain	1976–2017	R, multicenter	5083	3603/162/29/449/840	30–39	2230 (44.0)	–	–	2554 (81.4)	–
Zaghiyan et al[54]	2016	USA	1997–2007	R, single center	334	237/97/0/0/0	38	148 (44.3)	–	–	334 (100)	5.8
Bertucci Zoccali et al[55]	2019	USA	2000–2010	R, single center	411	411	36	171 (41.6)	151 (36.7)	256 (62.3)	359 (87.3)	5.2

Dashes indicate not specified.

*Mean follow-up.

CD indicates Crohn's disease; FAP, familial adenomatous polyposis; IC, indeterminate colitis; IPAA, ileal pouch-anal anastomosis; NL, Netherlands; R, retrospective; UC, ulcerative colitis; UK, United Kingdom; USA, United States of America.

which was reported in 27 studies. Eighteen studies reported the pouch type, and the majority used a J-pouch (86.2%). A stapled anastomosis was used in 48.3% of the procedures, which was reported in 20 studies.

Definitions and Diagnostic Criteria Used for IPAA-related Complications

Pouch failure was defined as the need for a permanent ileostomy with or without pouch excision in 26 of the studies[10,18,21–24,31–37,39,40,42,44,47,48,50,51,53,55]; 3 studies additionally included pouch revision.[16,20,41] Pouch failure was undefined in 4 studies.[19,46,49,54] Anastomotic leak was defined as any defect at the anastomotic site confirmed by imaging or during surgical reintervention in 7 studies[16,20,23,24,55,56] and was undefined in 9 studies.[21,32,33,36,41,48,49,52,53] Pelvic sepsis included pelvic abscesses with or without anastomotic leak[20,23,31,32,36,39,41,43,46,52] in 10 studies; included anastomotic leaks, pelvic abscesses, and fistulas in 2 studies[21,45]; and was undefined in 4 studies.[34,37,47,53] Fistula was defined as a fistula originating from anywhere in the pouch in 10 studies[16,20,23,31,33,34,39,44,50,53]; originating from the anastomosis only in 1 study[48]; and was undefined in 7 studies.[19,21,36,41,46,47,55] Stricture was defined as narrowing at the anastomotic site requiring dilation in 8 studies[16,33,36,39,44,46,48,50] and was undefined in 7 studies.[10,19,34,41,47,53,55] A diagnosis of CD was based on clinical and pathological findings in 5 studies.[24,37,42,44,55] In 2 other studies, the diagnosis was only based on clinical findings including severe inflammation of the pouch and proximal small bowel and strictures of the proximal small bowel and fistulae formation more than 3 months[54] or more than 6 months after surgery.[40] Four studies lacked a clear description of the diagnostic criteria used for a change in diagnosis from UC to CD after IPAA creation.[19,31,34,39] A diagnosis of pouchitis was based on clinical and endoscopic findings in 13 studies[23,33,35,39–41,44,46,49–51,54,55] and was mainly based on clinical symptoms in 2 studies.[19,36] Seven studies lacked a clear description of the diagnostic criteria used for pouchitis.[10,16,31,34,47,48,53]

Critical Appraisal and Risk of Bias

The overall risk of bias for each item of the JBI checklist across all included studies is presented in Figure, Supplemental Digital Content 2, http://links.lww.com/AOSO/A41. The study-level risk of bias for each individual study is presented in Figure, Supplemental Digital Content 3, http://links.lww.com/AOSO/A41. A funnel plot for pouch failure is presented in Figure, Supplemental Digital Content 4, http://links.lww.com/AOSO/A41. All studies were retrospective, although 13 studies prospectively collected their data.[10,19,20,31,33,34,37,41,47,49,51,54,55] One study collected their data in a partially prospective manner.[22] The inclusion of consecutive patients was not described in 27% (8/30) of the included studies, which suggests a risk of selection bias. Definitions for pouch-related complications and methods used for the assessment of one or more of these complications were lacking in 63% (19/30) of the studies. These findings suggest a moderate to high risk of detection bias.

Pouch Failure and IPAA-related Complications

The incidence of complications following IPAA is displayed in Tables 2 and 3. The overall pooled incidence of pouch failure was 6.7% (95% CI: 5.28–8.44, Figure 1). The sensitivity analysis revealed a pouch failure rate of 7.7% (95% CI: 5.56–10.59) for studies with a median follow-up of ≥5 years and 10.3% (95% CI: 7.24–14.30) for studies with a median follow-up of ≥10 years. Five studies reported 20-year cumulative pouch failure rates with a range of 6.7–18.2%[18,19,22,31,37] (Table 4). Pouch failure rates increased with follow-up time, although at 1 center, the pouch failure rate only marginally increased from 5.3% at 5-year follow-up to 6.7% at 30-year follow-up.[19] The majority of studies with long-term outcomes demonstrated a comparable pouch failure rate after 5 years (range 4.0–9.1%; Table 4), while the incidence of pouch-related complications varied widely among studies (Tables 2 and 3). In the 2 studies with the highest anastomotic leak rate (>14%), no pouch failure rate increase could be demonstrated (5.4% and 6.8%).[10,16] In some studies, the fistula rate was higher compared with the anastomotic leak rate[21,23,53] or pelvic sepsis rate.[19,31,34,46] In the majority (6/7) of the included studies that reported on both pouch-related fistula and a diagnosis of CD after IPAA creation, the fistula rate was substantially higher compared with rate of CD, which is a different entity.[16,19,31,34,39,44]

Predictors of Pouch Failure

Correlation analysis of the relationship between pouch-related complications and pouch failure of the included studies indicated that pelvic sepsis ($r = 51$, $P < 0.05$) and fistula ($r = 0.63$, $P < 0.01$) were significantly correlated with pouch failure (Table 5 and Figure 2). In addition, we performed a sensitivity analysis on the studies with a median follow-up of ≥5 years to identify which factor was the best predictor of long-term pouch failure. The fistula rate was the only factor that remained significantly correlated with pouch failure ($r = 0.77$, $P < 0.01$). There was no correlation between CD and fistula ($r = 0.13$, $P = 0.65$).

DISCUSSION

In this systematic review which included 30 studies comprising 22,978 patients, we observed a pooled pouch failure rate of 7.8% and 10.3% after a median follow-up of ≥5 and ≥10 years following IPAA, respectively. The definitions used for IPAA-related complications and reported outcomes following IPAA were highly variable. High volume expert centers[19–21] demonstrated favorable outcomes over population-based data.[22,46] Pouch failure was correlated with pelvic sepsis and pouch-related fistula. However, long-term pouch failure (≥5 years) was only correlated with pouch-related fistula. Our results suggest that only leaks without healing of the anastomosis resulting in fistula formation or chronic sinus are responsible for the failure rate. Not the leaks that are completely healed. This outcome is in line with a large cohort study including 3468 patients, which showed that fistula (hazard ratio, 2.2; 95% CI: 1.2–4.0) was significantly associated with pouch failure, while anastomotic leak was not (hazard ratio, 1.5; 95% CI: 0.75–3.0).[20] Data of the current review underlines the necessity to improve the management of anastomotic leaks, to prevent leaks from becoming a chronic anastomotic problem.

Over the last decade, pouch surgery has evolved through centralization and the incorporation of new techniques, including double stapled anastomosis and minimal invasive surgery. Still, pouch failure and pouch-related complication rates did not exhibit an improvement over results from a previously published systematic review, which reported pooled pouch failure rates (follow-up ≥5 years) of 4.7% (studies published between 2000 and 2009) and 8.5% (studies published before 2000).[2] Therefore, knowledge on IPAA-related outcomes should be improved (eg, using uniform definitions and data acquisition methods). Ultimately, this could lead to the identification of best practices and an improvement of outcomes.

This review demonstrated a lack of uniformity in the reporting of IPAA-related complications. The different definitions and diagnostic criteria used between studies for IPAA-related complications and time spans have complicated comparisons. For example, differences were found for the terms "short term" (ie, in hospital, <30 days, <90 days, before ileostomy closure) and "long term" (ie, after hospital discharge, ≥30 days, ≥90 days, after ileostomy closure). In addition, differences in clinical manifestations of the disease play a role. For example, an anastomotic defect can have different manifestations at various stages

TABLE 2.

Complications Following IPAA Procedures

	N	Pouch Failure n (%)	Anastomotic Leak n (%)	Pelvic Sepsis n (%)	Pouch-related Fistula n (%)	Stricture n (%)	Crohn's Disease de novo n (%)	Pouchitis n (%)
Carcamo	116	9 (7.5)	–	10 (8.6)	22 (19.0)	–	9 (7.8)	27 (23.3)
Cataneo	176	5 (4.2) n = 120	6 (3.4)	15 (8.5)	–	–	–	–
Dafnis	124	3 (2.4)	1 (0.8)	–	1 (0.8)	1 (0.8)	–	37 (33.0)
Die	139	42 (30.2)	–	17 (12.2)	41 (29.5)	14 (10.1)	7 (5.0)	30 (21.6)
Feinberg	3468	161 (4.6)	122 (3.5)	188 (5.4)	87 (2.5)	–	–	–
Hashimoto	119	9 (7.6)	–	–	–	–	–	26 (23.6) n = 110
Helavirta	352	42 (11.9)	44 (12.5)	61 (17.3)	42 (11.9)	49 (13.9)	–	134 (38.1)
Ikeuchi	944	28 (3.0)	–	21 (2.2)	–	–	12 (1.3)	–
Karjalainen	510	13 (2.5)	28 (5.5)	37 (7.3)	36 (7.1)	–	–	240 (47.1)
Karlbom	188	16 (8.5)	12 (6.4)	25 (13.3) n	11 (5.6)	32 (17.0)	2 (1.1)	44 (23.4)
Kayal	386	26 (6.7)	–	–	–	–	46 (11.9)	205 (53.1)
Landerholm	1720	103 (6.0)	–	–	–	–	–	–
Lee	212	10 (4.7)	15 (7.1)	37 (17.5)	20 (9.4)	18 (8.5)	–	75 (35.4)
Leowardi	294	37 (12.6)	–	–	–	–	0 (0.0)	–
Lightner/Farouk	1875	99 (5.3)	–	73 (4.8) n = 1508	205 (11.1) n = 1840	618 (33.6) n = 1840	46 (2.5) n = 1840	1130 (61.4) n = 1840
Lorenzo	185	20 (10.8)	–	–	32 (17.3)	24 (13.0)	13 (7.0)	53 (28.7)
Mark-Christensen	1991	295 (14.8)	–	244 (16.8) n = 1456	–	–	–	–
McCombie	121	14 (13.0) n = 108	–	9 (7.4)	30 (26.8) n = 112	17(15.2) n = 112	–	60 (55.6) n = 108
Mege	185	10 (5.4)	26 (14.1)	–	–	18 (9.7)	–	33 (17.8)
Mennigen	122	4 (3.3)	–	11 (9.0)	6 (4.9)	24 (19.7)	–	31 (25.4)
Rokke	134	13 (9.7)	6 (4.5)	–	6 (4.5)	6 (4.5)	–	35 (26.3)
Sahami	621	42 (6.8)	105 (16.9)	–	44 (7.1)	47 (7.6)	21 (3.4)	68 (11.0)
Sampietro	150	7 (5.1) n = 137	8 (5.3)	–	–	–	–	35 (23.3)
Tan	142	4 (2.8)	–	–	9 (6.3)	3 (2.1)	–	42 (29.6)
Uchino	2376	61 (2.6) n = 2349	176 (7.4)	–	–	–	16 (0.7)	–
Wasmuth	315	23 (7.3)	29 (9.5) n = 304	39 (12.8) n = 304	–	–	–	112 (35.6)
Wibmer	185	23 (12.4)	4 (2.2)	17 (9.2)	12 (6.5)	11 (6.0)	–	31 (16.8)
Worley	5083	239 (4.7)	168 (3.3)	478 (9.4)	239 (4.7)	–	–	–
Zaghiyan	334	13 (3.9)	–	–	–	–	42(17.8) n = 236	60 (18.0)
Zoccali	411	42 (10.2)	38 (9.3)	–	36 (8.8)	63 (15.3)	60 (14.6)	166 (40.4)

Dashes indicate not specified.

IPAA indicates ileal pouch-anal anastomosis.

TABLE 3.

Pooled Incidence of Complications Following IPAA With 95% CI

	Number of Studies	Number of Patients	Pooled Incidence (%) (95% CI)	Range (%)
Pouch failure	30	22,869	6.7 (5.28–8.44)	2.4–30.0
Pouch failure ≥5 yrs FU	19	12,994	7.7 (5.56–10.59)	2.4–30.0
Pouch failure ≥10 yrs FU	11	5314	10.3 (7.24–14.30)	2.4–30.0
Anastomotic leakage	16	14,479	6.3 (4.50–8.83)	0.8–16.9
Pelvic sepsis	16	14,884	9.2 (7.05–11.87)	2.2–17.5
Fistula	18	13,944	8.6 (6.07–11.94)	0.8–29.5
Stricture	15	4952	10.3 (6.63–15.60)	0.8–33.6
Crohn's disease de novo	11	7115	4.0 (1.93–8.04)	0.0–17.8
Pouchitis	22	6856	30.0 (23.41–37.62)	11.0–61.4

CI indicates confidence interval; FU, follow-up; IPAA, ileal pouch-anal anastomosis.

in the perioperative period such as abdominal sepsis, contained pelvic abscess, presacral sinus, anastomotic stricture, or pouch fistula. Therefore, it is necessary to obtain clear, detailed, and uniform data on how complications were scored. Study comparison could be improved if predefined definitions and diagnostic criteria for IPAA-related complications are used, as previously described by Fazio et al.[57]

Differences in timing and methods used for the assessment of anastomotic integrity may have contributed to the varying anastomotic leak rate ranging from 0.8% to 16.9%. In patients without primary defunctioning (only 16% in this study population), symptomatic leaks resulting in pelvic sepsis are usually diagnosed within 1 week following IPAA.[58] However, asymptomatic leaks in a defunctioned anastomosis will only become

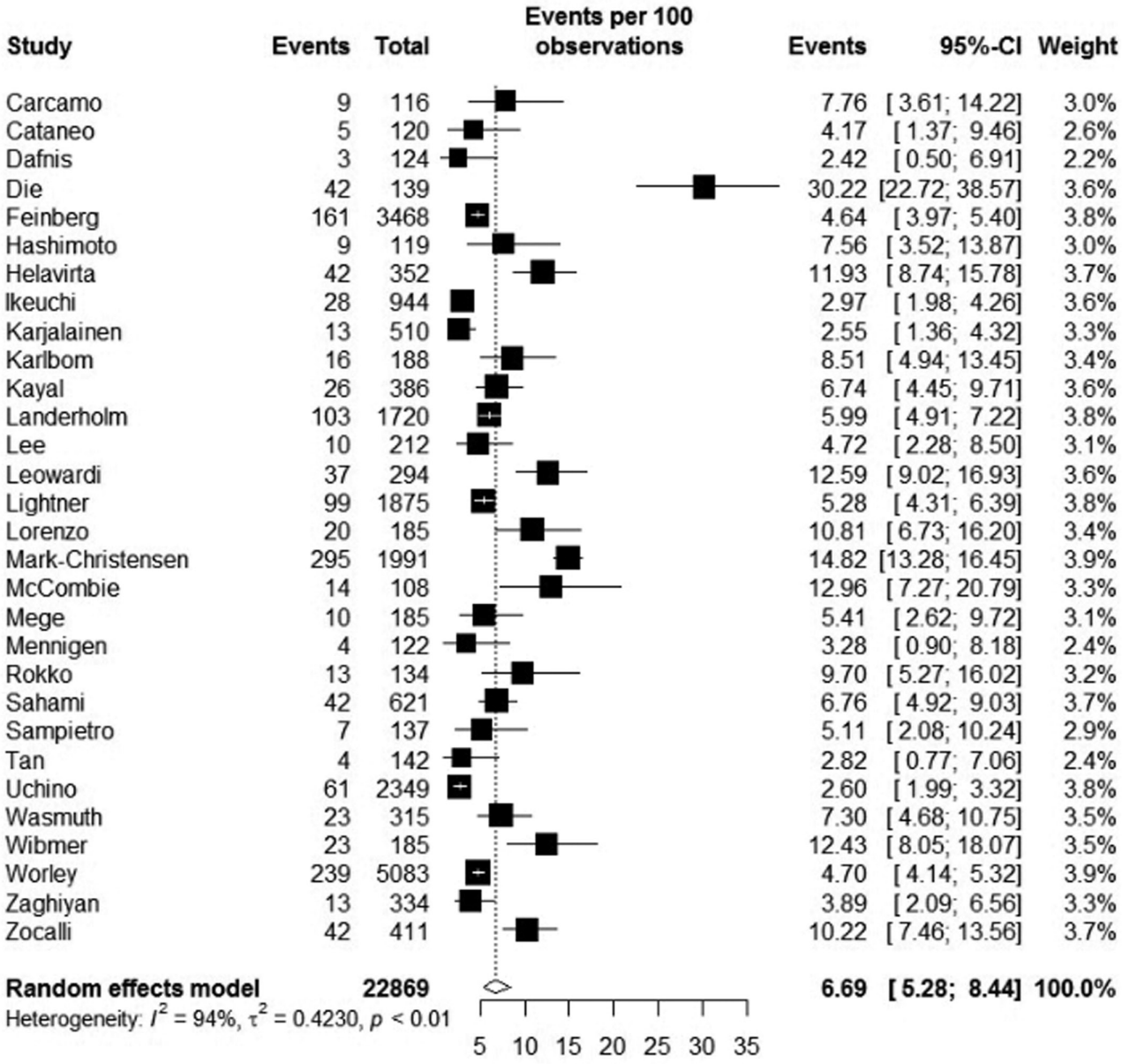

FIGURE 1. Plot of the individual studies presenting pouch failure rates with 95% CI and the overall incidence of pouch failure with 95% CI. CI indicates confidence intervals.

apparent in the majority of patients after assessment of the anastomosis through pouchoscopy, a pouchogram, CT imaging with transanal contrast, or MR.[59] The diagnostic accuracy of pouchoscopy or pouchogram to detect peripouch infection is lower compared with CT imaging.[60–62] When no cross-sectional imaging is performed, especially in diverted patients, there is a potential risk for a delay of diagnosis or misdiagnosis of the anastomotic leakage. This might lead to an underestimation of the actual leak rate. In some patients, an insufficiently treated chronic anastomotic leak can mimic chronic pouchitis or CD of the pouch.[63]

The diagnosis of CD of the pouch in UC patients remains challenging because there are no uniform diagnostic criteria. In the majority of the studies included, a diagnosis of CD was based solely on clinical findings (ie, stricturing or fistulizing disease) without pathologic confirmation. Sossenheimer et al assessed the relationship between abnormal pouchography and long-term pouch complications. The authors suggest that CD of the pouch might be overly assigned, as all patients with contrast extravasation at the initial pouchogram who lost their pouch were at some point labeled as having CD based on clinical findings.[59] Lightner et al. analyzed 35 patients with UC who underwent pouch excision for CD, of which 16 patients had fistulizing disease.[64] When analyzing the patients with fistulizing disease, the anastomotic leak rate was 0% (0/4) in the group with a pathologic diagnosis of CD versus 91.6% (11/12) in the group without a pathologic diagnosis of CD.[64] Differentiation between fistulizing disease caused by technical complications or CD is important, as the former can be managed surgically and does not require immunosuppressive treatment. Non-CD-related fistulas should be considered a late manifestation of anastomotic leaks due to delayed diagnosis or unsuccessful treatment.

Data of the current review suggest that there is room for improvement in the management of anastomotic leaks, trying to avoid the occurrence of chronic leaks and fistula formation. One way of doing that is through early identification of leaks using

TABLE 4.

Overview of Studies Reporting on Cumulative Long-term Pouch Failure Rates

	N	5 yr	10 yr	15 yr	20 yr	30 yr
Carcamo	116	–	3.5%	–	6.9%	–
Feinberg	3468	–	6.0%	–	–	–
Ikeuchi	944	–	3.0%	–	11.0%	–
Karlbom	188	5.4%	6.9%	–	–	–
Landerholm	1720	4.0%	6.0%	–	8.0%	–
Leowardi	294	7.7%	11.3%	15.5%	–	–
Lightner	1875	5.3%	6.3%	6.5%	6.7%	6.7%
Mark-Christensen	1991	9.1%	12.1%	–	18.2%	–
Sahami	621	6.0%	11.5%	–	–	–
Sampietro	150	7.0%	–	–	–	–
Uchino	2376	–	4.2%	–	–	–

Dashes indicate not specified.

TABLE 5.

Correlations Between IPAA-related Complications and Pouch Failure

	Spearman's correlation	Spearman's correlation*
Anastomotic leakage	r = 0.32, *P* = 0.22	r = 0.60, *P* = 0.07
Pelvic Sepsis	**r = 0.51, *P* < 0.05**	r = 0.53, *P* = 0.14
Fistula	**r = 0.63, *P* < 0.01**	**r = 0.77, *P* < 0.01**
Stricture	r = 0.21, *P* = 0.45	r = 0.12, *P* = 0.78
Crohn's disease de novo	r = 0.04, *P* = 0.90	r = 0.24, *P* = 0.57
Pouchitis	r = 0.08, *P* = 0.71	r = 0.13, *P* = 0.65

Bold font indicates statistical significance.

*Sensitivity analysis included studies with a median follow-up of ≥5 years.

close observation with C-reactive protein and computed tomography with anal contrast. Routine cross-sectional imaging should be considered, especially in diverted patients with potential silent leaks. Proactive management of an anastomotic leak can be achieved with conventional techniques as transanal or CT-guided drainage[65] and more modern techniques as endoluminal vacuum-assisted closure.[14] Endoluminal vacuum-assisted closure has been shown to effectively salvage the anastomosis at an early stage, preventing pouch failure due to chronic leaks/anastomotic fistula.[14] Unfortunately, this technique is not available in all countries.

The diversion rate of the included studies ranged from 23.3% to 100%, which reflects the lack of consensus regarding routine fecal diversion. Primary diverting ileostomy was performed least frequently in Finland.[23,36] The main reason to divert is to mitigate the consequence of anastomotic leakage and improve pouch survival. A systematic review including 1486 patients showed that nondiversion was associated with an increased risk of anastomotic leak, while long-term outcomes of pouch survival were similar to those of diverted patients.[66] However, a nationwide cohort study from Denmark showed that primarily nondiverted pouches had a significantly higher risk of pouch failure.[22] In contrast, several other studies showed no relation between a protective ileostomy and pouch failure.[13,15,24,48,52,67]

This review has several limitations. As discussed before, heterogeneity across the included studies impairs the objective comparison of study outcomes. Many studies combined UC and other diagnoses and did not separate outcomes based on diagnosis. In addition, incomplete data registration has led to a large number of unspecified diagnosis, which might be related to the voluntary nature of some registries. Due to the lack of individual patient data, the effect of patient (ie, preoperative status, medication use) and surgical characteristics (ie, procedural stages, hand-sewn versus stapled anastomosis, laparoscopic versus open approach) on postoperative outcomes could not be assessed. Furthermore, besides detection and reporting bias, it is likely that publication bias exists because centers with poor outcomes may be less eager to publish their results. The strength of this systematic review is that it comprised multiple large cohort series with a considerable long-term follow-up, providing a comprehensive overview of the currently available long-term outcomes following IPAA.

In conclusion, the pouch failure rate did not improve over time when compared with prior analysis.[2] Anastomotic leaks and long-term sequela are still a major problem. The key finding of this systematic review is that the long-term pouch failure rate was neither correlated with pelvic sepsis nor anastomotic leakage but only with pouch fistula. Anastomotic fistula, presacral sinus, and chronic leak are all indicators of a chronic anastomotic problem. All efforts should therefore be taken (ie, proactive diagnosis and management) to avoid acute leaks from becoming a chronic leak. To facilitate further comparative studies and identify best practices, a prospective registration of patients undergoing IPAA, with predefined standardized outcomes and standardized assessment of anastomotic integrity is necessary. For this reason, the MIRACLE project was initiated, a prospective European multicenter study, which determines long-term anastomotic integrity in patients who underwent a restorative proctocolectomy for UC (Trial NL 9083). The ECCO UR-CARE registry will be used to accommodate prospective registration of patient, surgical, and medical treatment characteristics, postoperative management, and outcomes. This registration system will provide a better understanding of changes in practice over time and their effects on outcomes. Variation in practices might help to identify best practices, resulting in the optimization of long-term pouch preservation.

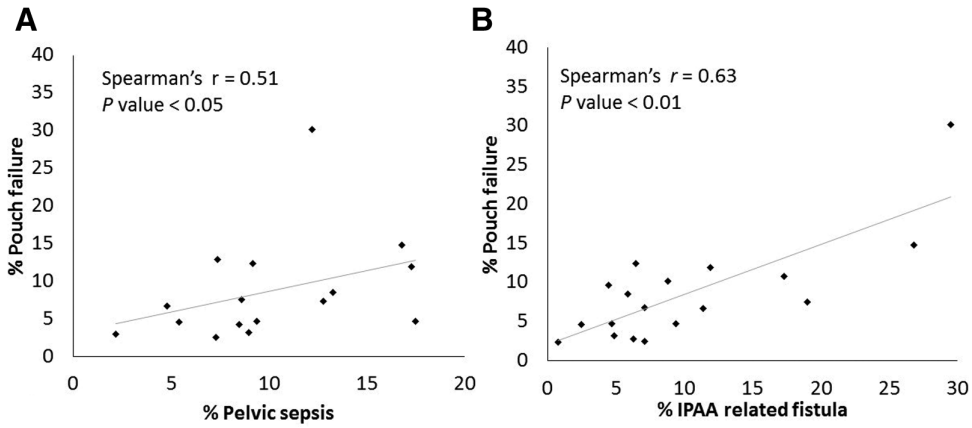

FIGURE 2. Correlation between pelvic sepsis and pouch failure (A), and IPAA-related fistula and pouch failure (B).

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