

Systematic review

A systematic review of outcomes and quality of life after ileorectal anastomosis for ulcerative colitis



Mohammed Al-Rashedy*, Tanmoy Mukherjee, Alan Askari, Shashank Gurjar

Luton & Dunstable University Hospital Trust, Lewsey Road, Luton LU4 0DZ, United Kingdom

ARTICLE INFO

Keywords:

Ulcerative colitis
Ileo-rectal anastomosis
Quality of life
Anastomotic leak

ABSTRACT

Background and study aims: Ileorectal anastomosis (IRA) is one option for restoring bowel continuity in patients who have undergone subtotal colectomy for ulcerative colitis (UC). This systematic review aims to assess short- and long-term outcomes after IRA for UC, including anastomotic leak rates, IRA failure (as defined by conversion to pouch or end stoma), cancer risk in the rectal remnant, and quality of life (QoL) post-IRA surgery.

Materials & methods: The Preferred Reporting Items for Systematic Reviews and Meta-Analysis checklist was used to demonstrate the search strategy. A systematic review of PubMed, Embase, Cochrane library, and Google Scholar from 1946 to August 2022 was undertaken.

Results: This systematic review included 20 studies, representing 2538 patients who underwent IRA for UC. The mean age ranged from 25 to 36 years and the mean postoperative follow-up ranged between 7 and 22 years. The overall leak rate reported across 15 studies was 3.9 % (n = 35/907) ranging from 0 % to 16.7 %. The failure of IRA (requiring conversion to pouch or end stoma) as reported across 18 of the studies was 20.4 % (n = 498/2447). The risk of developing cancer in the remaining rectal stump following IRA was reported by 14 studies and was accumulatively 2.4 % (n = 30/1245). Five studies reported on patient QoL using a variety of different instruments and 66.0 % of patients (n = 235/356) reported a “high” QoL score.

Conclusion: IRA was associated with a relatively low leak rate and a low risk of colorectal cancer in the rectal remnant. However, it does carry a significant failure rate which invariably requires conversion to an end stoma or the formation of an ileoanal pouch. IRA provided a QoL to most of the patients.

Introduction

Ulcerative colitis (UC) is an inflammatory condition characterized by continuous inflammation throughout the colon and significantly increases the risk of developing colorectal cancer, with up to 1 in 5 patients developing cancer after 30 years of diagnosis [1]. A substantial proportion of patients (up to 30 %) will require colectomy in their lifetime for either intractable inflammation or dysplasia/cancer development [2,3]. Patients have two broad options after colectomy, one is an end ileostomy and the other is to attempt to re-establish intestinal continuity. Restorative surgery in UC has been performed for over 60 years, with the first procedures dating back to 1953 by Stanley Aylett and colleagues [4]. Restorative surgery has essentially-two main approaches, one is ileorectal anastomosis (IRA), and the other, is ileal pouch-anal anastomosis (IPAA). Both have unique characteristics in

terms of bowel function, success, complications, and longevity.

From the outset, IRA mainly aims to rid the patient of a permanent ileostomy, allowing for the return to normal activities and by extension improvement of the patient’s quality of Life (QoL). However, IRA has its own set of problems despite this laudable aim, both in terms of early postoperative complications, including anastomotic leak, prolonged ileus [5], increased stool frequency [6], recurrent proctitis [7], and the impact on long-term fertility particularly in female patients [8]. Furthermore, the risk of developing cancer in the remnant rectum persists [9] although a recent cohort study reported that the absolute risk of cancer development in the rectal remnant was only 1.6 % at 10 years [10]. Patients with IRA will require continuous surveillance and monitoring for dysplasia/cancer development because a portion of the rectum is in place. Additionally, a proportion of patients may require further surgery in the form of a permanent stoma or conversion to IPAA

Abbreviations: UC, Ulcerative colitis; IRA, Ileorectal anastomosis; QoL, Quality of life; IPAA, Ileal pouch-anal anastomosis; FAP, familial adenomatous polyposis; NIHE, National Institute of Health Economics.

* Corresponding author.

E-mail address: malrashedy@gmail.com (M. Al-Rashedy).

<https://doi.org/10.1016/j.ajg.2023.01.007>

Received 23 May 2022; Accepted 15 January 2023

Available online 20 February 2023

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due to IRA failure.

Therefore, IRA has been largely superseded by IPAA over the last few decades. First described by Sir Alan Parks in 1978 [11], IPAA has gained popularity largely because IPAA permits better control over bowel movements and less urgency and obviates the need for intensive cancer surveillance of the rectal remnant. However, IRA is still performed in current practice in patients who want to avoid more extensive pelvic surgery and thereby avoid the risk of reduced fecundity and erectile dysfunction. While much has been published with regards to surgical outcomes between IRA and IPAA in terms of surgical outcomes and function, there remains little in the literature with regards to the quality of life and symptom experienced post-IRA surgery. This systematic review aims to assess short- and long-term outcomes after IRA for UC, including leak rates, IRA failure (as defined by conversion to pouch or end stoma), dysplasia/cancer risk in the rectal remnant, and QoL post-IRA surgery.

Materials and methods

A literature search was performed using MEDLINE, PubMed database, Ovid, and Google Scholar from 1946 to August 2022. The following keywords were used: ileorectal anastomosis, ulcerative colitis, outcomes, and QoL. The search was restricted to articles published in the English language about human adults. The latest study was used in instances where articles were published by the same group of authors, using the same data. Manual searching of references was performed for further articles. A Preferred Reporting Items for Systematic Reviews and meta-Analyses flow diagram was used to demonstrate the search methodology.

Inclusion and exclusion criteria

All articles (including both adults and children) that reported one or more outcomes, including anastomotic leak, failure rate, dysplasia/cancer development, and QoL after IRA, were included in this systematic review. Studies that reported outcomes post IRA surgery for conditions other than UC (such as familial adenomatous polyposis [FAP] or chronic constipation) were excluded from the analysis. Similarly, commentary, letters, or other systematic reviews on the topic were excluded.

Data extraction and quality assessment

Data were extracted from the included studies using a predefined proforma by two authors (TM and AA) and validated by a third author (MAR). Information on study characteristics, such as year of publication, study timeframe, age of included patients, and follow up was recorded. Data on leak rates, failure of IRA (resulting in stoma and pouch formation), dysplasia/cancer development, and patient QoL were collected. Quality assessment of studies was performed using the National Institute of Health Economics (NIHE) case series studies checklist (<https://www.ihe.ca/publications/ihe-quality-appraisal-checklist-for-case-series-studies>) and the Newcastle-Ottawa Scale (NOS) for population studies (https://www.ohri.ca/programs/clinical_epidemiology/oxford.asp).

Outcomes and data reporting

Four main outcomes of interest were reported, including short-term outcomes, such as a peri-operative anastomotic leak, and long-term outcomes, such as IRA failure, cancer and dysplasia development, and QoL post-IRA formation.

- **Outcome 1 – Anastomotic Leak:** rate of the anastomotic leak as reported by the authors.
- **Outcome 2 – Failure:** conversion to a pouch, takedown of IRA, and end stoma formation.

- **Outcome 3 – Dysplasia & Cancer:** rate of developing dysplasia and/or cancer in the rectal remnant post-IRA surgery.
- **Outcome 4 – Quality of life:** using a variety of methods and therefore reported as “low” or “high” according to the article’s reporting criteria and the QoL measure used by the authors.

Results

Study characteristics

Electronic searching yielded a total of 208 articles. Manual searching of references identified a further 1 article, giving a total of 209 articles suitable for abstract reviewing (Fig. 1). After removing duplicates, commentary, reviews, and letters, 152 articles remained for review of manuscripts. Of these, 132 were excluded because they did not meet the inclusion criteria and did not present outcomes of interest, thereby leaving a total of 20 studies in this systematic review. The total number of patients across all studies was 2538 patients (Table 1), and all the studies were either single institution case series or observational cohort studies. The studies varied in their reporting of the age of the included patients, with some studies reporting a mean while others reported a median. This was also the case for the reporting of the length of follow-up.

Various studies reported different outcomes, including 15 studies reporting anastomotic leak (Outcome 1), 18 reporting on IRA failure (Outcome 2), 14 reporting on the occurrence of dysplasia and cancer post-IRA (Outcome 3), and 5 reporting on QoL post-IRA (Outcome 4). Study quality was variable, with one of the population-based studies using Swedish data (Landerholm [12]) scoring highly on the NOS checklist. Several of the case series, notably, studies by Tonelli, Andersson, and da Luz scored well on the NIHE case series studies checklist, scoring 17, 16, and 16 out of 20, respectively. Additionally, the more historical case series scored poorly on the checklist due to the lack of detail provided in the manuscripts regarding population, study methodology, and follow-up.

Outcome 1 – anastomotic leak

A total of 15 studies (including 907 patients) reported an anastomotic leak rate in the early postoperative period with a mean study to follow-up ranging from 3.5 to 22 years (Table 2). The overall mean leak rate was 3.9 % (n = 35/907) with the highest reported leak rate being 16.7 % (n = 3/18) and the lowest being 0 %.

Outcome 2 – ileorectal anastomosis failure

Ileorectal anastomotic failure was defined as the need for taking down the anastomosis and conversion to an end stoma or conversion to an ileoanal pouch (Table 3). The overall rate of failure was 20.4 % (n = 498/2447) across 18 studies. The highest failure rate reported by a study was 61.1 % (n = 11/18) published in 1981 and the lowest was 4.7 % reported by Aylett’s original series of 300 patients in 1966. Most studies reported the time between IRA surgery and failure. The largest study using population data and including 1112 patients reported a 10-year failure rate of 27.0 %, a similar figure to that reported by smaller studies by Andersson [15], da Luz [20], and Lepisto [25].

Outcome 3 – dysplasia and cancer

The incidence of dysplasia/cancer post-IRA was reported by 14 of the studies (Table 4), giving a collective rate of 4.5 %, although the actual rate of cancer was markedly lower (2.4 %, n = 30/1245). The highest rate of cancer was found in the study by da Luz [20] comprising 86 patients in which 7 patients (n = 7/86, 8.1 %) developed cancer. The time from IRA surgery to cancer development was very sparsely reported, ranging from 4 to 18 years.

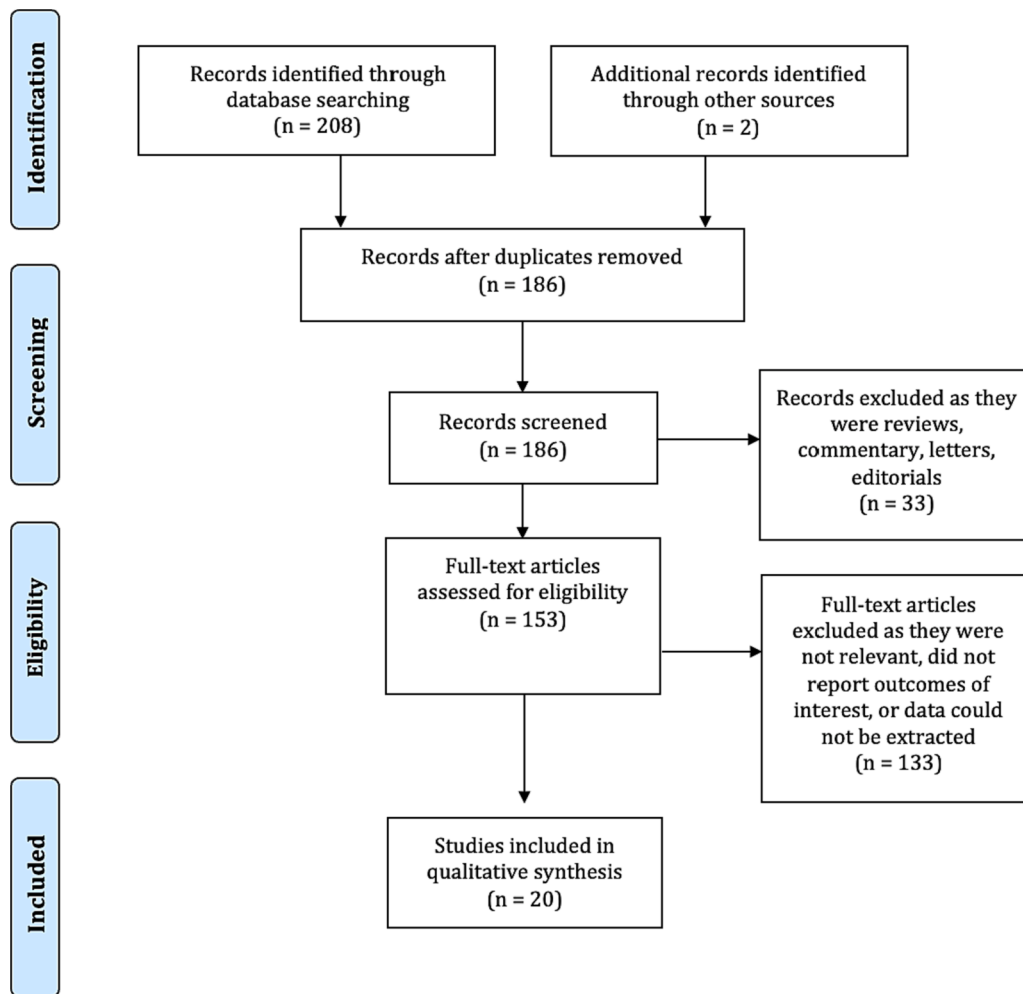


Fig. 1. PRISMA flow chart that demonstrated the search strategy and the included studies in this systematic review.

Outcome 4 – quality of Life

Five studies ($n = 356$, Table 5) reported QoL outcomes and 66.0 % ($n = 235/356$) of the population self-reported as having the highest QoL category. Significant variability was found in the quality of life reported with the proportion of patients reporting a high QoL, with the highest reported by Abdalla (92.1 %) [13] and the lowest by da Luz (36.4 %) [20]. Different QoL measures were used across the studies, including SF-36, and the Cleveland Clinic Global Quality of Life questionnaires. Two of the studies (Oakley [27] and Pastore [28]) did not report the type of questionnaire used in their studies.

Discussion

This systematic review mainly revealed that IRA surgery after subtotal colectomy for UC is associated with a low leak rate and a high QoL as reported by the patients. However, a relatively high failure rate was observed, with 18.4 % of patients requiring conversion to either IPAA or end stoma. The failure rate in the literature has been reported to be even higher, with some studies quoting failure rates of up to 27.4 % [13] although a large meta-analysis of 14,996 patients published in 2012 deemed the failure rate to be much lower, at 7.5 % [32].

The nature or cause of IRA failure is exactly ascertained based on the data from the current review; however, several factors have been identified in the literature. Suitable patient selection criteria for candidates for this procedure include evidence of reasonable sphincter function and rectum-sparing UC. The selection of appropriate patients for

IRA is of utmost importance and the high variability of success reported in the literature may reflect the variable patient selection.

One marker that has been traditionally used to determine “failure” post-IRA has the number of reported bowel movements that patients have in 24 h. The number of bowel movements has been reported to average six times a day or even more [15,20], with a considerable impact on daily activity and QoL, particularly in a younger, more active patient group. Nocturnal evacuation and subsequent disruption to sleep patterns can be troublesome in patients living with an IPAA although the IPAA appears to be even more problematic from this perspective [15,33].

QoL differences between IRA and the ileoanal pouch have been the subject of much discussion in the literature. Some authors reported no difference in QoL between the two procedures [34]. The multi-center Dutch study encompassing 279 patients explored differences in QoL using both SF-36 and the European Organization for Research and Treatment of Cancer QLQ-CR38 questionnaire. This study, using the SF-36 questionnaire, revealed that both the IPAA and IRA groups scored very similarly on both questionnaires, and both had lower scores compared to the general population. The only area where IPAA appeared to perform marginally better was in the domain of “defecation problems” using the EORTC QLQ-CR38 tool. The study concluded no discernible difference in QoL between the two procedures and that QoL should not be used as a basis for selecting one procedure over another. A more recent study by Urso and colleagues in 2020 reported similar findings, wherein bowel-specific QoL questions score lower in patients undergoing IRA, without difference in overall QoL between patients

Table 1
General characteristics of all 20 studies included in this systematic review. NS = not stated, QoL = quality of life.

Study	Year Published	Study Years	Mean/Median Age	Mean/Median Follow-Up (years)	Total IRA Patients (n)	Outcomes Studied				
						Leak	Failure	Cancer	Quality of Life	Quality Score
Abdalla [13]	2020	1992–2006	25.8 (6.4–57.2)	12.5	38	X	X	✓	✓	14/20
Albrechtsen [14]	1981	1969–1978	34.7 (12–76)	6.0 (2.0–11.0)	18	✓	✓	✓	X	12/20
Andersson [15]	2014	1992–2006	34.2	5.4 (1.6–9.2)	105	✓	✓	✓	X	16/20
Aylett [16]	1966	1952–1965	NS	NS	300	X	✓	✓	X	10/20
Backer [17]	1988	1951–1979	NS	NS	59	✓	✓	✓	X	5/20
Baker [18]	1970	1953–1968	9.0–66.0	NS	39	✓	✓	X	X	11/20
Börjesson [19]	2006	1997–2003	NS	3.5	32	✓	✓	X	X	12/20
da Luz [20]	2010	1971–2006	28.0 (14.0–63.0)	11.0 (1.0–37.0)	86	✓	✓	✓	✓	16/20
Elton [21]	2003	1990–1999	33	NS	18	✓	✓	X	X	11/20
Jones [22]	1986	1958–1984	NS	NS	39	✓	✓	X	X	10/20
Khubchandani [23]	1994	1960–1992	NS	22.0 (0.5–30)	68	✓	✓	✓	X	11/20
Landerholm [12]	2017	1960–2010	39.3 (28.0–51.9)	12.4 (6.5–16.6)	1112	X	✓	X	X	8/9
Leijonmarck [24]	1990	1955–1984	32.0 (10.0–67.0)	13.0 (4.0–27)	51	✓	✓	✓	X	7/9
Lepisto [25]	2005	1978–2000	43.0 (22.0–66.0)	18.0 (3.7–25.2)	20	✓	✓	✓	X	14/20
Melville [26]	1994	1976–1990	NS	NS	95	X	✓	✓	X	11/20
Oakley [27]	1985	1960–1982	30.4 (9.0–72.0)	7.9 (2.0–14.0)	145	✓	✓	✓	✓	7/20
Pastore [28]	1997	1974–1990	40.6	6.5 (1.3–11.3)	48	✓	✓	✓	✓	11/20
Romano [29]	1987	1960–1985	NS	7.2	86	X	✓	✓	X	10/20
Saito [30]	1995	1963–1994	NS	7.5	53	✓	X	X	X	11/20
Tonelli [31]	2016	1986–2010	35.8 (16.0–73.0)	11.5 (2.0–24.3)	126	✓	✓	✓	✓	17/20
					2538					

Table 2
Leak rates among patients undergoing IRA. NS = not stated.

Study	Year Published	Study Years	Mean/Median Age	Mean/Median Follow-Up (years)	Outcome 1 – Leak		
					Total(n)	Leak (n)	% Leak Rate
Albrechtsen	1981	1969–1978	34.7 (12–76)	6 (2–11)	18	3	16.7 %
Andersson	2014	1992–2006	34.2	5.4 (1.6–9.2)	105	3	2.9 %
Backer	1988	1951–1979	NS	NS	59	0	0.0 %
Baker	1970	1953–1968	9–66	NS	39	6	15.4 %
Börjesson	2006	1997–2003	NS	3.5	32	1	3.1 %
da Luz	2010	1971–2006	28 (14–63)	11 (1–37)	86	2	2.3 %
Elton	2003	1990–1999	33	NS	18	1	5.6 %
Jones	1986	1958–1984	NS	NS	39	3	7.7 %
Khubchandani	1994	1960–1992	NS	22.0 (0.5–30)	68	3	4.4 %
Leijonmarck	1990	1955–1984	32 (10–67)	13 (4–27)	51	2	3.9 %
Lepisto	2005	1978–2000	43 (22–66)	18.0 (3.7–25.2)	20	1	5.0 %
Oakley	1985	1960–1982	30.4 (9–72)	7.9 (2–14)	145	3	2.1 %
Pastore	1997	1974–1990	40.6	6.5 (1.3–11.3)	48	2	4.2 %
Saito	1995	1963–1994	NS	7.5	53	2	3.8 %
Tonelli	2016	1986–2010	35.8 (16–73)	11.5 (2–24.3)	126	3	2.4 %
					907	35	3.9 %

undergoing IRA and those who undergo segmental colonic resection [25].

One of the main criticisms levied against IRA is that the rectal remnant serves as a potential site for either proctitis or adenocarcinoma (or both). The risk of cancer is certainly very real and has been reported widely in the literature. However, remembering that the risk of cancer development is small in patients with UC is important but arguably higher in patients with FAP; with some studies reporting a 30-year cancer risk of 57 %, although the sample size in this study was rather small (n = 27) [21]. The risk of cancer appears to be lower in UC, ranging from 2 % to 6 % [21,23,26,28,35]. The cumulative risk calculated in the present study puts the risk at 2.4 % and the risk of dysplasia at 2.1 %. Therefore, discussing, and offering IRA as an alternative to IPAA in patients with UC seems reasonable. A young patient wanting to avoid the potential risk of reduced fecundity in females and erectile dysfunction in males, as well as the higher morbidity in both that comes

with an extensive pelvic dissection during IPAA, may well want to consider IRA, especially because evidence suggests that IRA function is not worse (and in fact in some studies, better) than IPAA [36].

The main limitation of this systematic review is the very nature of the included studies which tend to be retrospective in nature and often include data from a single institution. Hence, there may be an element of bias in the reported outcomes and questions may be raised as to whether all the eligible consecutive patients have been entered into the analyses. Furthermore, the heterogenous nature of the populations included in many of the studies, which encompasses many disease processes and not just UC, makes ascertaining the specific symptomology of patients post-IRA difficult. The present analysis only included patients who underwent IRA, specifically for UC; however, questions remain as to how many of these patients may have had other or even concurrent conditions.

In conclusion, IRA in selective patients confers a reasonable quality

Table 3
Failure rate of IRA across all studies, NS – not stated, IPAA – Ileal Pouch Anal Anastomosis (IPAA).

Study	Year Published	Study Years	Mean/Median Age	Mean/Median Follow-Up (years)	Outcome 2 – Failure					
					Total (n)	Conversion to IPAA (n)	Conversion to Stoma (n)	Overall Failure (n)	Failure Rate (%)	Time From IRA to Failure in Years (Range)
Albrechtsen	1981	1969–1978	34.7 (12–76)	6.0 (2.0–11.0)	18	3	6	11	61.1%	4.0 (2.0–12.0)
Andersson	2014	1992–2006	34.2	5.4 (1.6–9.2)	105	5	6	14	13.3%	5 y: 10.1%, 10 y: 24.1%
Aylett	1966	1952–1965	NS	NS	300	0	14	14	4.7%	NS
Backer	1988	1951–1979	NS	NS	59	0	8	13	22.0%	7.0 (2.0–18.0)
Baker	1970	1953–1968	9.0–66.0	NS	39	0	5	11	28.2%	NS
Börjesson	2006	1997–2003	NS	3.5	32	0	4	4	12.5%	NS
da Luz	2010	1971–2006	28.0 (14.0–63.0)	11.0 (1.0–37.0)	86	32	16	48	55.8%	10 y: 26.0%, 20 y: 54.0%
Elton	2003	1990–1999	33	NS	18	0	2	2	11.1%	NS
Jones	1986	1958–1984	NS	NS	39	0	8	8	20.5%	5.4 (1.0–18.0)
Khubchandani	1994	1960–1992	NS	22.0 (0.5–30)	68	0	8	8	11.8%	8.0 (2.0–10.0)
Landerholm	2017	1960–2010	39.3 (28.0–51.9)	12.4 (6.5–16.6)	1112	76	NS	265	23.8%	10 y: 27.3%
Leijonmarck	1990	1955–1984	32.0 (10.0–67.0)	13.0 (4.0–27)	51	0	29	29	56.9%	10 y: 49.0%
Lepisto	2005	1978–2000	43.0 (22.0–66.0)	18.0 (3.7–25.2)	20	0	7	7	35.0%	5 y: 16.0%, 10 y: 31.0%, 20 y: 44%
Melville	1994	1976–1990	NS	NS	95	17	1	21	22.1%	5 y: 16.0%
Oakley	1985	1960–1982	30.4 (9.0–72.0)	7.9 (2.0–14.0)	145	0	10	10	6.9%	6 (1.5–15.5)
Pastore	1997	1974–1990	40.6	6.5 (1.3–11.3)	48	0	5	7	14.6%	NS
Romano	1987	1960–1985	NS	7.2	86	0	0	7	8.1%	NS
Tonelli	2016	1986–2010	35.8 (16.0–73.0)	11.5 (2.0–24.3)	126	5	2	19	15.1%	5 y: 8.0%, 10 y: 13.0%, 20 y: 15.0%
					2447	138	131	498	20.4%	

Table 4
Development of dysplasia or cancer in the rectal remnant post-IRA. NS – not stated.

Study	Year Published	Study Years	Mean/Median Age	Mean/Median Follow-Up (years)	Outcome 3 – Dysplasia/Cancer				
					Total (n)	Dysplasia (n)	Cancer (n)	Total Dysplasia or Cancer (n)	Total Dysplasia or Cancer %
Abdalla	2020	1992–2006	25.8 (6.4–57.2)	12.5	38	1	0	1	2.6 %
Albrechtsen	1981	1969–1978	34.7 (12–76)	6 (2–11)	18	0	2	2	11.1 %
Andersson	2014	1992–2006	34.2	5.4 (1.6–9.2)	105	1	2	3	2.9 %
Aylett	1966	1952–1965	NS	NS	300	0	3	3	1.0 %
Backer	1988	1951–1979	NS	NS	59	0	1	1	1.7 %
da Luz	2010	1971–2006	28 (14–63)	11 (1–37)	86	15	7	22	25.6 %
Khubchandani	1994	1960–1992	NS	22.0 (0.5–30)	68	0	2	2	2.9 %
Leijonmarck	1990	1955–1984	32 (10–67)	13 (4–27)	51	3	0	3	5.9 %
Lepisto	2005	1978–2000	43 (22–66)	18.0 (3.7–25.2)	20	1	0	1	5.0 %
Melville	1994	1976–1990	NS	NS	95	1	1	2	2.1 %
Oakley	1985	1960–1982	30.4 (9–72)	7.9 (2–14)	145	1	3	4	2.8 %
Pastore	1997	1974–1990	40.6	6.5 (1.3–11.3)	48	0	1	1	2.1 %
Romano	1987	1960–1985	NS	7.2	86	0	4	4	4.7 %
Tonelli	2016	1986–2010	35.8 (16–73)	11.5 (2–24.3)	126	3	4	7	5.6 %
					1245	26	30	56	4.5 %

Table 5
Quality of Life (QoL) post-IRA as reported by different studies.

Study	Year Published	Study Years	Mean/Median Age	Mean/Median Follow-Up (years)	Outcome 4 – Quality of Life				
					QoL Total Pop (n)	Low QoL	High QoL	% High QoL	QoL Measure
Abdalla	2020	1992–2006	25.8 (6.4–57.2)	12.5	38	3	35	92.1 %	SF-36
da Luz	2010	1971–2006	28 (14–63)	11 (1–37)	22	0	8	36.4 %	Cleveland Clinic Global Quality of Life (CGQL)
Oakley	1985	1960–1982	30.4 (9–72)	7.9 (2–14)	145	3	75	51.7 %	Not Stated
Pastore	1997	1974–1990	40.6	6.5 (1.3–11.3)	25	4	21	84.0 %	Not Stated
Tonelli	2016	1986–2010	35.8 (16–73)	11.5 (2–24.3)	126	30	96	76.2 %	Cleveland Clinic Global Quality of Life (CGQL)
					356	40	235	66.0 %	

of life and serves as an alternative to IPAA for UC. However, there remains a relatively high risk of failure with a significant proportion of patients requiring conversion to permanent stoma or IPAA. Therefore, prudent patient selection and the management of expectations of this patient group are of paramount importance in increasing the likelihood of success. Well-designed multi-center randomized control trials pitting IRA, IPAA, and end-stoma against each other in a three-arm study may well answer some of these key questions which remain largely unanswered. The reality is that such a trial is not feasible because of the limitation of choice and significant differences in the offered approach.

Funding declaration

The authors have not received any funding for this work.

Authors' contributions

This project was conceptualized by AA, MAR, and SG. The data were extracted, analyzed, and tabulated by AA and TM (including all figures and tables). The manuscript was written by MAR, TM, and AA, and edited and checked for scientific content by SG. All authors have contributed significantly to the study design.

Declaration of competing interests

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

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