




Diverted versus undiverted restorative proctocolectomy for chronic ulcerative colitis: an analysis of long-term outcomes after pouch leak short title: outcomes after pouch leak

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Abstract

Background The safety of undiverted restorative proctocolectomy (RPC) is debated. This study compares long-term outcomes after pouch leak in diverted and undiverted RPC patients.

Methods Data were obtained from a prospectively maintained registry from a single surgical practice. One-stage and staged procedures with an undiverted pouch were considered undiverted pouches; all others were considered diverted pouches. The outcomes measured were pouch excision and long-term diversion defined as the need for loop ileostomy at 200 weeks after pouch creation. Regression models were used to compare outcomes.

Results There were 317 diverted and 670 undiverted pouches, of which 378 were one-stage procedures. Pouch leaks occurred in 135 patients, 92 (13.7%) after undiverted, and 43 (13.6%) after diverted pouches. Eighty-six (64%) leaks were diagnosed within 6 months of pouch creation. Undiverted patients underwent more emergent procedures within 30 days of pouch creation ($p < 0.01$). Pouch excision occurred in 14 (33%) diverted patients and 13 (14%) undiverted patients ($p = 0.01$). Thirteen (32%) diverted patients and 18 (21%) undiverted patients ($p = 0.17$) had ileostomies at 200 weeks after surgery. In multivariable analyses, diverted patients had a higher risk of pouch excision (HR 3.67 $p < 0.01$), but similar rates of ileostomy at 200 weeks (HR 1.8, $p = 0.19$) compared to undiverted patients.

Conclusions Despite a likely selection bias in which “healthier” patients undergo an undiverted pouch, our data suggest that diversion does not prevent pouch excision and the need for long-term diversion after pouch leak. These findings suggest that undiverted RPC is a safe procedure in appropriately selected patients.

Keywords Ulcerative colitis · Restorative proctocolectomy · Ileostomy

Introduction

Nearly 50% of patients with chronic ulcerative colitis (CUC) will undergo surgery within their lifetime. For many CUC patients, restorative proctocolectomy (RPC) with ileal pouch creation and ileal pouch-anal anastomosis (IPAA) represents a

surgical solution for their colonic disease. When successful, RPC avoids the need for a permanent ileostomy and is generally associated with good quality of life and functional outcomes [1–5].

One controversial aspect of RPC surgery is the need for a temporary diverting loop ileostomy (DLI) at the time of pouch creation. Leaks occur in an estimated 4–17% of patients undergoing RPC. A pouch leak may lead to pelvic sepsis, fistula, stricture, and ultimately, pouch failure [6–9]. Many surgeons use primary diversion at the time of pouch creation in an effort to lessen the immediate, negative consequences associated with pouch leaks, including emergent reoperation and even death [10]. By decreasing pelvic contamination when a leak occurs, diversion may also improve long-term pouch function, though this potential benefit has not been well studied [11, 12].

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Diverting ileostomy is associated with its own risks and complications including up to a 7% obstruction and 2–3% leak rate at the subsequent closure site, as well as the need for readmissions secondary to high output and dehydration [13]. Additional surgery is always required to close the stoma. To date, there are several studies suggesting that, in a highly select subset of patients, an undiverted pouch is safe, and in some centers, carries a low risk of leaks and other pouch-related complications [7, 10, 14].

The aim of this study was to describe the long-term outcomes in patients who suffered a pouch leak after diverted and undiverted restorative proctocolectomies. Specifically, we examined pouch excision and the need for long-term proximal diversion rates in this population.

Materials and methods

Data were collected from a prospectively maintained RPC database encompassing all patients undergoing RPC in one surgical practice. Three surgeons performed the abdominal pelvic portion, but two surgeons, SG and JB, did the vast majority (98%) of the perineal portion. The institutional review board of the Icahn School of Medicine at Mount Sinai approved this study.

All patients who had undergone RPC for CUC from 1990 to 2014 and had suffered a pouch leak were included. Pouch leaks were classified as any evidence of pouch leak at any time after RPC. This included both symptomatic and asymptomatic leaks discovered radiologically either before or after ileostomy

closure among diverted patients [15]. Patients with missing data regarding surgical dates and outcome data were excluded from the analysis.

Patients were considered to have undiverted RPC (U-RPC) if they had undergone one-stage RPC or two-stage RPC consisting of a subtotal colectomy followed by an undiverted pouch. All other pouch procedures were considered diverted RPC (D-RPC) including patients undergoing RPC with a DLI and those having subtotal colectomy followed by pouch with DLI.

Patient selection for diversion was individualized and based on preoperative assessments by surgeons and gastroenterologists. Clinical criteria such as the use of immunomodulating medications, general health, and nutrition were considered, though no specific cutoffs were routinely used. On occasion, patients who were scheduled to have an undiverted pouch based on their preoperative assessment required diversion due to technical difficulties with the pouch or tension at the IPAA which could not be resolved. In these cases, the decision to divert was made intraoperatively.

The outcomes of interest were pouch excision or the need for long-term proximal diversion with an ileostomy. Long-term diversion was defined as having primary or secondary ileostomies in place at the 200-week time-point following the pouch procedure, and was analyzed as a binary, categorical outcome. The 200-week time-point was chosen based on the median time to secondary ostomy creation in undiverted patients. This would allow us to capture a significant proportion of the patients requiring long-term diversion.

Additional postoperative complications and interventions recorded included surgical site infections (SSIs), urinary tract

Fig. 1 Study population

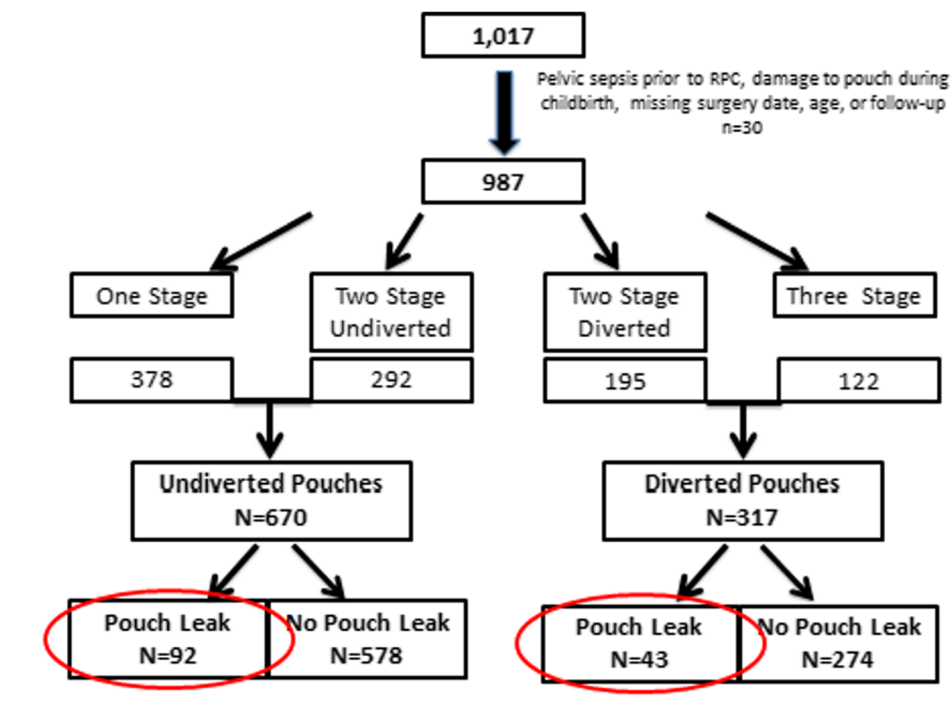


Table 1 Demographic and clinical characteristics ($n = 135$)

	Diverted ($n = 43$)	Undiverted ($n = 92$)	<i>p</i>
Age years, mean (SD)	36.6 (14)	35.1 (13)	0.54
Male n (%)	24 (56)	46 (50)	0.53
Disease duration years, median (IQR)*	5.0 (12)	3.0 (11)	0.08
Albumin ⁺ > 3 g/Dl n (%)	19 (79)	56 (79)	0.98
Prednisone n (%)	29 (32)	13 (30)	0.88
Other n (%)			
5-ASA**	12 (46)	29 (41)	0.68
CSA ⁺⁺	3 (18)	6 (9)	0.31
6-MP***	7 (32)	20 (29)	0.77

* $n = 123$ + $n = 95$ ** $n = 96$ ++ $n = 83$ *** $n = 92$

infections (UTIs), procedures performed, and timing of pouch leak diagnosis. Finally, we collected data concerning all procedures performed because of the pouch leak.

Univariate analyses comparing demographic, clinical, and operative data were conducted using *t* test and the Mann-Whitney non-parametric alternative where appropriate. Categorical variables were analyzed using chi-square test. Operative details and postoperative complications were analyzed in a similar fashion. Operative procedures after leak were compared using Poisson regression. The Kaplan-Meier estimator and log-rank test were used to compare the risk of pouch excision. Chi-square test was used to compare rates of pouch failure.

We used stepwise selection with a $p < 0.05$ threshold of significance to select preliminary covariates for our multivariable models. In addition, clinically relevant demographic, clinical, and operative variables were considered, and tested for possible collinearity before inclusion into the final model. For the purposes of multivariable modeling, missing albumin and duration of disease data were imputed using the mean of the respective variables within each cohort. Pouch excision was analyzed using a Cox proportional hazards model. Long-term diversion was analyzed with a logistic regression model after excluding patients with less than 200 weeks of follow-up. Sensitivity analyses including only patients with pouch leaks diagnosed within 6 months of RPC were also conducted. For all analyses, a p value of less than 0.05 was considered statistically significant.

Table 2 Operative and pathologic characteristics ($n = 135$)

	Diverted ($n = 43$)	Undiverted ($n = 92$)	<i>p</i>
Lap-assisted n (%)	6 (14)	11 (12)	0.74
Mucosectomy n (%)	33 (77)	81 (88)	0.09
Stapled n (%)	0	0	–
Tension n (%)	11 (26)	8 (9)	0.01
Follow-up weeks, median (range)	1186.1 (5–1392)	848 (9–1252)	< 0.01

Results

Between 1990 and 2014, 987 patients underwent RPC. In total, 317 were diverted (D-RPC) and 670 were undiverted (U-RPC) including 378 completed as a one-stage procedure. Of the 1017 patients, there were 30 exclusions for missing surgical dates, date of last follow-up, or age at the time of surgery. In total, 135 (13.6%) patients were diagnosed with a pouch leak after surgery. Among patients who leaked, 43 (13.6%) were diverted and 92 (13.7%) were not diverted (Fig. 1).

Demographic and clinical variables for all patients who experienced a postoperative leak are shown in Table 1. Patient cohorts were similar with respect to age at the time of surgery, the proportion of male patients, albumin levels, and duration of disease before surgery (Table 1).

Operative details for pouch leak patients are shown in Table 2. The cohorts had similar rates of laparoscopically assisted procedures, mucosectomy, and handsewn anastomoses. All pouch leak patients had handsewn anastomoses. Patients in the D-RPC cohort were more likely to have tension at the anastomosis, after all measures to reduce tension were performed, as reported by the operating surgeon. Overall, patients in the D-RPC group had longer follow-up reflecting the fact that U-RPC is a more recent addition to the RPC surgical technique.

The rate of surgical site infections, urinary tract infections, and small bowel obstructions was similar between the groups

Table 3 Postoperative complications ($n = 135$)

	Diverted ($n = 43$)	Undiverted ($n = 92$)	p
SSI n (%)	1 (2)	7 (8)	0.23
UTI n (%)	1 (2)	2 (2)	0.96
Ileus/small bowel obstruction n (%)	4 (9)	18 (20)	0.13

(Table 3). The timing of pouch leaks in D-RPC and U-RPC is shown in Table 4. Overall, U-RPC patients presented earlier with pouch leaks than D-RPC patients. The median time to leak diagnosis after pouch creation was 31 weeks in D-RPC patients and 3 weeks in U-RPC patients. Among the D-RPC patients, there was nearly an equal number of pouch leaks diagnosed before and after ileostomy closure.

With respect to procedures related to pouch leak, U-RPC patients were more likely to require a procedure within 30 days of pouch leak diagnosis, and they were more likely to require creation of an unplanned ileostomy (Table 5). The number of patients who underwent unplanned procedures or operations to salvage the pouch, including fistula or primary pouch repair, advancement flap, seton placement, incision, and drainage of abscess or bypasses of pouch inflow at any time after pouch surgery, was similar between the groups.

Fourteen (33%) D-RPC patients and 13 (14%) U-RPC patients underwent pouch excision. (Table 6, Fig. 2) This difference was statistically significant on univariate analysis ($p = 0.01$). A total of 31 patients had an ileostomy in situ at the 200-week time-point after surgery (Table 6). Of these, 13 (32%) had diverted pouches and 18 (21%) had undiverted pouches. This difference was not significantly different on univariate analysis ($p = 0.17$).

On multivariable analysis controlling for age, albumin level, tension, duration of disease, prednisone use, and mucosectomy, pouch excision remained more common after D-RPC (Table 7). In a sensitivity analysis including only the 86 patients whose leaks were diagnosed within 6 months of RPC, D-RPC patients were still at increased risk for pouch excision (HR 4.0, $p = 0.05$). This finding did not reach statistical significance ($p = 0.05$) likely due to the smaller number of patients analyzed (Table 8). There was no difference in long-term diversion rates between the D-RPC and U-RPC groups (OR 1.8, $p = 0.19$).

Table 4 Timing of pouch leak ($n = 135$)

	Diverted ($n = 43$)	Undiverted ($n = 92$)	p
Time from pouch creation to leak diagnosis* weeks, median (range)	31.6 (75)	3.0 (40)	< 0.01
Leak diagnosed within 30 days* n (%)	7 (17)	51 (57)	< 0.01
Before ileostomy closure n (%)	21 (49)	NA	–
After ileostomy closure n (%)	22 (51)	NA	–

* $n = 132$; patients excluded for unclear leak date

Discussion

The results of this study suggest that diversion at the time of pouch surgery does not mitigate the long-term sequela of pouch leak. Diverted and undiverted patients who had leaks suffered similar long-term diversion rates. In this non-randomized study, we would expect a selection bias whereby patients undergoing an undiverted pouch had more favorable preoperative and operative characteristics. It is important to note, however, that our diverted and undiverted patients were similar with respect to preoperative immunosuppressive use and albumin level. This suggests that an undiverted pouch is a safe procedure in a perhaps underestimated number of CUC patients, and that an undiverted pouch does not subject patients to inferior long-term outcomes when a pouch leak does occur.

Our study, as well as others, demonstrates a higher rate of pouch excision among patients diverted at their original pouch procedures [7, 16]. It is likely that the patient factors which prompted diversion also contribute to the need for pouch excision, and that a diverting ileostomy made at initial pouch surgery neither prevents pouch-related leaks nor ensures a successful long-term outcome should a leak occur.

The outcomes of interest were pouch excision or the need for long-term proximal diversion. Pouch excision clearly represents a failure of the intent of the procedure. Long-term diversion, a more inclusive parameter, was defined as the presence of a proximal ileostomy at 200 weeks after pouch creation. This definition attempted to capture the various manifestations of pouch dysfunction which can occur at any time after pouch surgery, but do not necessarily culminate in pouch excision [17]. It is not a perfect outcome, however, since some patients with ostomies at 200 weeks may end up being reversed, just as patients without ostomies at 200 weeks may end up being diverted. Still, it is a useful marker of a patient

Table 5 Procedures attributable to pouch leak ($n = 135$)

Procedure type	Diverted ($n = 43$)	Undiverted ($n = 92$)	p
Patients with unplanned trips to OR within 30 days of IPAA leak diagnosis n (%)	5 (12)	41 (45)	< 0.01
Patients undergoing unplanned ostomies within 200 weeks of pouch creation* n (%)	10 (27)	53 (60)	< 0.01
1 unplanned ileostomy n (%)	9 (22)	48 (55)	< 0.01
> 1 unplanned ileostomy n (%)	3 (7)	4 (5)	0.53
Patients undergoing salvage operations throughout total follow-up n (%)	32 (74)	72 (78)	0.62

* $n = 128$ patient with at least 200 weeks' follow-up

with pouch dysfunction significant enough to merit having an ostomy in situ years after pouch surgery. Our findings indicate that initially diverted patients were more likely to undergo pouch excision, while undiverted patients underwent more pouch salvage procedures and emergent procedures within 30 days of pouch formation. Initially diverted and undiverted patients had similar rates of long-term diversion after pouch creation. These findings suggest that diversion at the time of pouch surgery may lessen the short-term impact of some leak-related complications, but diversion does not influence long-term failure rates.

The reasons for continued diversion long after pouch creation are varied. In some cases, patient preference may delay ileostomy closure for reasons unrelated to pouch complications. Most commonly, however, diversion in the long term after pouch surgery is due to a pouch-related problem. Chronic fistula, strictures, incontinence, and unremitting pouchitis may lead to continued diversion with an initial ileostomy or secondary diversion after several years if more conservative management has failed. These findings also underscore the need for a more inclusive measure of long-term pouch dysfunction.

Our data suggest that symptomatic leaks were identified earlier after pouch creation among U-RPC patients than D-RPC patients. This is consistent with previous studies, and is perhaps expected since diverted patients are more likely to have “silent” leaks [15]. The fact that 51% of D-RPC patients who had pouch leaks were diagnosed after ileostomy closure may suggest that radiographic pouch studies may miss small leaks which become symptomatic once the pouch becomes functional.

The 13% pouch leak rate reported in our overall pouch cohort is higher than those reported in similar large series. In

the largest observational study to date, including over 4000 patients from two different institutions, the authors found equivalent leak rates among diverted and undiverted patients (5.5%, 3.9%, respectively) [14]. However, two separate analyses from the Cleveland Clinic Foundation came to differing conclusions. A matched study between diverted and undiverted patients suggested a higher leak rate among undiverted pouches, whereas a prospective database study showed similar leak rates [8]. The authors of the largest meta-analysis to date, including 17 studies and more than 1400 patients, concluded that the pouch leak rate was higher for the U-PRC cohort (OR 2.37, $p < 0.01$) [16].

Our higher leak rate was likely related to a more inclusive definition of pouch leak. In this series, all leaks occurring at any time after pouch creation were included. Additionally, we included leaks identified only radiographically as well as chronic fistula tracts and abscesses. While some groups would consider any leak occurring 6 months or more after pouch surgery as a manifestation of Crohn's disease, others have suggested that pelvic septic complications may occur several years after surgery, without evidence of this alternative diagnosis [18]. Given this controversy, and our inability to conclusively exclude Crohn's disease in patients with delayed leaks, we conducted a sensitivity analysis including only the leaks which had been diagnosed within 6 months of pouch surgery. Our 8.5% leak rate in this subset analysis was more consistent with other studies, and did not affect our findings.

Identifying clinical variables that predict an advantage of diversion at pouch surgery was not the aim of this study. However, several groups have attempted this [14, 19, 20]. One nomogram has been devised which combines factors such as preoperative steroid use, age, sex, indication for

Table 6 Long-term outcomes after pouch leak ($n = 135, 128$)

	Diverted ($n = 43$)	Undiverted ($n = 92$)	p
Pouch excision n (%)	14 (33)	13 (14)	0.01
Long-term diversion* n (%)	13 (32)	18 (21)	0.17

* $n = 128$ patient with at least 200 weeks' follow-up

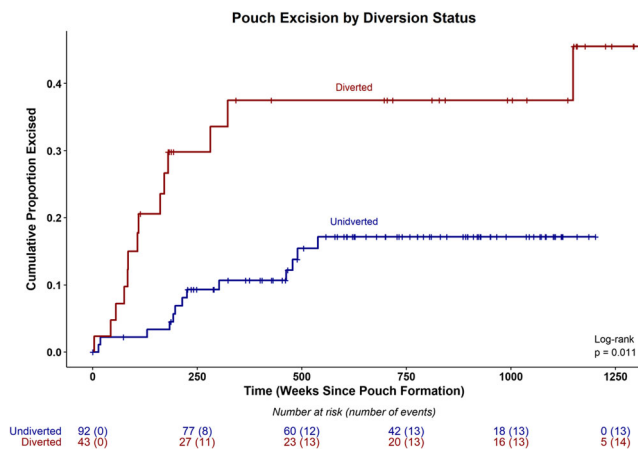


Fig. 2 Kaplan-Meier curve of pouch excision by diversion status

procedure, and anastomotic technique. This effort has met with limited success [14]. This is an area that clearly merits continued research.

The principal strength of this study is the size of the cohort and the large number of undiverted pouches in our series. In addition, this data originates from a prospective, single-practice, single-institution database allowing for analysis of several key operative and postoperative data [6]. Previous studies examining outcomes after diverted and undiverted pouches reported results in fewer than 300 U-RPC patients, with rare exception [7, 10, 14].

The weakness of this study lies in our incomplete data regarding the preoperative clinical status of our patients and its non-randomized design. Aside from medication and albumin data, we cannot adjust fully for these patients' clinical

Table 7 Multivariable analyses: pouch excision and pouch failure

Pouch excision	Hazard ratio	CI	<i>p</i>
Diverted RPC	3.7	1.7–8.2	< 0.01
Age	1.1	1.0–1.1	< 0.01
Albumin < 3 mg/Dl	1.3	0.4–3.9	0.66
Tension	0.9	0.3–2.7	0.90
Duration of disease (years)	1.0	1.0–1.0	0.99
Prednisone	0.5	0.2–1.2	0.11
Mucosectomy	0.1	0.0–0.6	0.02
Long-term diversion*	Odds ratio		
Diverted RPC	1.8	0.7–4.5	0.19
Age	1.0	1.0–1.1	0.10
Albumin < 3 mg/Dl	0.9	0.5–4.8	0.43
Tension	1.0	0.3–3.5	0.88
Duration of disease (years)	1.0	0.9–1.0	0.61
Prednisone	0.6	0.2–1.5	0.24
Mucosectomy	0.6	0.2–2.1	0.39

**n* = 128 patient with at least 200 weeks' follow-up

Table 8 Multivariable analyses of patients with diagnosed pouch leaks within 6 months of pouch creation (*n* = 86): pouch excision and long-term diversion

Pouch excision	HR	CI	<i>p</i>
Diverted RPC	4.0	1.0–16.2	0.05
Age	1.1	1.0–1.1	0.08
Albumin < 3 mg/Dl	2.4	0.4–13.6	0.34
Tension	2.8	0.5–17.3	0.27
Duration of disease (years)	1.1	1.0–1.2	0.19
Prednisone	0.6	0.1–2.5	0.43
Mucosectomy	0.0	0.0	> 0.99
Long-term diversion*	OR		
Diverted RPC	2.3	0.4–6.3	0.56
Age	1.0	1.0–1.1	0.34
Albumin < 3 mg/Dl	1.1	0.5–8.5	0.31
Tension	1.2	0.4–7.4	0.47
Duration of disease (years)	1.0	1.0–1.1	0.64
Prednisone	0.9	0.3–2.9	0.81
Mucosectomy	0.7	0.2–4.3	0.93

**n* = 79 patients with at least 200 weeks' follow-up

condition leading up to surgery. However, as one of the largest referral centers for inflammatory bowel disease in the country, we see patients with a wide spectrum of disease severity, and would expect our population to be comparable to those in other referral centers. Most previous studies examining this topic have also been observational [16]. Surgeons divert for both patient-related and intra-operative reasons. These include a challenging pelvic dissection, tension at the anastomosis, poor nutritional status, and elevated doses of immunosuppressants. A trial randomizing assignment of diversion status is a challenging endeavor. Only one such study has been completed to date [21].

Conclusions

In summary, diversion by proximal ileostomy at the time of pouch creation does not mitigate the long-term risk of pouch excision or the need for long-term diversion among patients who suffer a pouch leak. Patients with pouch-related leaks who were diverted at initial pouch surgery fared worse in the long term than undiverted patients. The reasons for these findings are likely multifactorial and related to the reasons why patients were selected for diversion in the first place. Our findings suggest that an undiverted pouch is a safe procedure in the short and long term for a select group of patients. Future studies should continue to explore surgeon and patient factors that may help to identify those patients most likely to benefit from diversion at the time of pouch creation.

Author's contribution Conception or design: Widmar, Munger, Gorfine, Chessin, Popowich

Bauer acquisition, analysis, or interpretation of data: Widmar, Munger, Gorfine

Drafting of manuscript: Widmar, Munger, Mui, Gorfine, Chessin, Popowich, Bauer

Critical revision: Widmar, Munger, Mui, Gorfine, Chessin, Popowich, Bauer

Compliance with ethical standards

The institutional review board of the Icahn School of Medicine at Mount Sinai approved this study.

Conflict of interest The authors declare that they have no conflict of interest.

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