



Colorectal Conditions

Early ileal pouch anal anastomosis for ulcerative colitis in children: Similar outcome to delayed pouch construction despite higher comorbidity

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ABSTRACT

Background: Children with ulcerative colitis (UC) may undergo a staged approach for restorative proctocolectomy and ileal pouch anal anastomosis (IPAA). Previous studies in adults suggest a decreased morbidity with delayed pouch creation, but pediatric studies are limited. We compared outcomes for delayed versus early pouch construction in children.

Methods: Patients with UC undergoing IPAA were selected from the National Surgical Quality Improvement Program Pediatric database from 2012 to 2018. Patients were categorized as early (2-stage) or delayed (3-stage) pouch construction based on Current Procedural Terminology codes. Our primary outcome was any adverse event. We used a multivariable logistic regression model to assess the relationship between timing of pouch creation and adverse events.

Results: We identified 371 children who underwent IPAA: 157 (42.3%) had early pouch creation and 214 (57.6%) had a delayed pouch. Those with an early pouch creation were more likely to have exposure to immunosuppressants (11% vs. 5%, $p = 0.017$) and steroids (30% vs. 10%, $p < 0.001$) at the time of surgery. After controlling for patient characteristics, there were no significant differences in adverse events between the two groups.

Conclusions: Children undergoing early pouch creation have increased exposure to steroids and immune suppressants; nevertheless, no differences in adverse events were identified.

Level of evidence: II

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Children and adolescents make up 15%–20% of the total patient population with ulcerative colitis (UC), and the estimated incidence in North America is 1–4 per 100,000 per year [1–3]. Pediatric-onset UC tends to be greater in extent and have a worse disease course compared to ulcerative colitis in the adult-onset population [4]. Owing to concerns about the long-term side effects of medical management, particularly the impact of poor nutritional status and long-term steroid use on growth [5–7], colectomy is often recommended for children who are unable to achieve good symptomatic control on maximal medical therapy [2]. Within 5 years of diagnosis 19% of children will require a colectomy, and within 10 years of diagnosis this rate increases to 30% to 40% [4,8,9]. The definitive surgical procedure of choice for medical refractory UC is the total proctocolectomy with ileal pouch-anal anastomosis (IPAA) [2,10].

IPAA is typically done as a two- or three-stage procedure. The two-stage or “early” pouch procedure is traditionally performed by completing the total proctocolectomy and ileal pouch creation initially with placement of a diverting loop ileostomy. The second stage of the opera-

tion is an ileostomy takedown [11]. Advantages of an early pouch procedure are typically a shorter hospital stay, less exposure to anesthetic and less time with an ileostomy [12]. The traditional three-stage or “delayed” pouch procedure is performed by completing a total colectomy with end ileostomy at the first stage, followed by completion proctectomy and the ileal pouch creation with diverting loop ileostomy at the second stage, and finally an ileostomy take down at the third stage [11]. Surgeons have elected to use a delayed pouch procedure in patients on steroids or with severe malnutrition that might put them at increased risk for surgical complications [2]. Single institution studies have demonstrated both early and delayed pouch procedures have good long-term outcomes in pediatric patients [13,14]. Given these limited studies, there remains concerns about whether or not early pouch formation has a greater risk of short-term adverse events, as the patients may be higher risk surgical candidates owing to their medication use and nutritional status at the time of ileal pouch creation.

Evidence to guide surgical decision-making in pediatric UC patients is sparse and treatment strategy primarily relies on surgeon judgment [2,15]. Studies comparing early versus late pouch creation in an adult population have shown that patients undergoing a delayed pouch reconstruction are at lower risk of unplanned reoperation, as well as

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major and minor adverse events [11]. However, this issue has not been studied in a pediatric population. We hypothesized that children would have lower complications and therefore be more suitable to undergo early IPAA despite potential modifiable surgical risks. To accomplish this, we used a large multi-institutional sample to assess the effects of early versus late pouch creation in a pediatric population on adverse events.

1. Methods

1.1. Patient selection and primary exposure

The National Surgical Quality Improvement Program Pediatric (NSQIP-P) program is a joint effort by the American College of Surgeons and the American Pediatric Surgical Association to track and improve 30-day surgical outcomes in children and neonates [16,17]. Currently NSQIP-P includes 134 hospitals across the United States including free-standing children's hospitals as well as children's hospitals within a larger hospital [17]. We included all patients in the NSQIP-P Public Use File from 2012 to 2018 with a diagnosis of Ulcerative Colitis (International Classification of Diseases, Ninth Revision [ICD-9] code 556 or ICD-10K51) and a Current Procedural Terminology (CPT) code for ileal pouch anal anastomosis (CPT codes 44,158, 44,211, and 45,113). Similar to prior work, we compared the stage of the surgery where the pouch formation took place, which was identified using the CPT codes shown above [11]. Patients who underwent pouch formation at the time of colectomy were classified as undergoing an early pouch creation (CPT codes 44,158, 44,211, and 44,157) [11]. Those who underwent colectomy without pouch creation followed by pouch creation at a later date were classified as delayed pouch creation (CPT 45,113, 45,119, 45,397) [11]. Patients with a diagnosis of Crohn's disease, those who had sepsis present in the 48 h prior to surgery, and those who underwent urgent or emergent procedures were excluded from the analysis. This project was approved by the University of Utah Institutional Review Board.

1.2. Primary and secondary outcomes

The primary outcome of interest was the occurrence of any major or minor adverse event. A major adverse event was defined as organ space surgical site infection, sepsis, septic shock, acute renal failure, time on a mechanical ventilator greater than 48 h, hospitalization greater than 30 days, and death. A minor adverse event was defined as wound disruption, deep incisional surgical site infection, superficial surgical site infection, and deep venous thrombosis or thrombophlebitis requiring therapy. Secondary outcomes of interest were unplanned reoperation, unplanned readmission, and postoperative length of stay.

1.3. Covariates

NSQIP-P includes patient demographic variables including age, race, ethnicity, and gender. Patient comorbidities are also included in the database including body mass index (BMI), asthma, liver/biliary/pancreatic (LBP) disease, preoperative immunosuppressant and steroid use, nutritional support, and American Society of Anesthesiologists Physical Status Classification (ASA class). Included operative variables were operative time, operative technique (laparoscopic versus open), and blood transfusion within 48 h of surgery.

1.4. Statistical analysis

All statistical analyses were performed using R 3.5.3. All statistical tests were two-tailed and a p-value <0.05 was considered significant. We first performed a univariate analysis to assess the relationship between early and delayed pouch creation and patient characteristics and outcomes. Continuous variables were summarized with mean and

standard deviation (SD) and compared between early and delayed pouch groups using a t-test. Categorical variables and indicators of adverse events were compared between groups using chi-square or Fisher's exact tests. A Fisher's exact test was used when the minimum expected frequency rule was not met for a chi-square test [18].

Univariable and multivariable logistic regression is used to assess the relationship between early or delayed pouch procedures and the outcome of any in hospital adverse event following surgery, which occurred in 54 of the 375 cases. The power of the model to detect an effect size was calculated using the Cohen's F-statistic [19–21] and it was determined that our model had a 95% power to detect a medium effect size for our primary outcome. We also repeated this model adjusting for covariates, including age, race/ethnicity, immunosuppressant use, steroid use, and open approach. Covariates were selected from presurgery demographic variables based on clinical significance or a significant association to early versus delayed pouch, while limiting our variables to no more than one predictor variable per five events [22]. There were no missing values among the variables selected for multivariable analysis. Odds ratios (ORs), 95% confidence intervals (CIs), and p-values are reported from this model.

Similar models were constructed for our secondary outcomes of unplanned reoperation and readmission. A gamma regression of postoperative length of stay was created with the same predictor variables as in the logistic models. Because gamma regression does not allow for values of 0 in the response, those with a length of stay of 0 are removed (there were 3). Estimates of the multiplicative difference, 95% CIs, and p-values are reported.

2. Results

2.1. Study population

From 2012 to 2016 we identified 371 patients who underwent an IPAA for ulcerative colitis; there were 157 patients who underwent early pouch procedures and 214 who underwent delayed pouch procedures. Baseline characteristics were compared between patients who underwent early pouch procedures and those who underwent late pouch procedures in Table 1. The mean age of patients was 14 years and the majority were white. There were no significant differences between the two groups with regards to age, gender, body mass index (BMI), or diagnosis of asthma. Patients who underwent a delayed pouch procedure were less likely to be non-Hispanic white race/ethnicity compared to patients who underwent an early pouch procedure.

Patients who underwent early pouch creation had more comorbidities than those who underwent delayed pouch creation including increased rates of LBP disease (5% vs 0%, $p = 0.002$) and increased exposure to immunosuppressants (11% vs 5%, $p = 0.017$) and steroids (30% vs 10%, $p < 0.001$). There were no statistically significant differences in nutritional support or ASA class between the two groups. With regards to operative technique, patients who underwent an early pouch procedure had longer operative times (mean 323 (SD 123) vs 293 (110), $p = 0.015$) and were less likely to have an open procedure (34% vs 58%, $p < 0.001$).

2.2. Unadjusted outcomes

On univariate analysis there was no significant difference in rates of any adverse event (16% vs 13%, $p = 0.36$), any major event (9% vs 7%, $p = 0.63$) or any minor event (10% vs 7%, $p = 0.49$) between the early and delayed pouch groups (Table 2). There were no significant differences in rates of unplanned reoperation between the early and late pouch groups (13% vs 11%, $p = 0.54$) or rates of readmission (27% vs 22%, $p = 0.23$). On univariate analysis, mean surgery to discharge length of stay was greater in the early pouch group (mean 7.4 (SD 5.2) vs 6.2 (4.1), $p = 0.030$, Table 2).

Table 1

Patient characteristics.

| Variable* | Type/level | Early (N = 157) | Delayed (N = 214) | P-value | Test |
|------------------------------------|-----------------------|-----------------|-------------------|---------|------|
| Age (years) | [Mean (SD)] | 14.3 (3.1) | 14.2 (3.0) | 0.78 | 1 |
| Gender | Female | 88 (56%) | 104 (49%) | 0.11 | 3 |
| | Male | 68 (43%) | 110 (51%) | | |
| | Nonbinary | 1 (1%) | 0 (0%) | | |
| | Other/unknown | 121 (77%) | 141 (66%) | | |
| Race/ethnicity | Non-Hispanic white | 36 (23%) | 73 (34%) | 0.026 | 2 |
| BMI | [mean (SD)] | 21.5 (5.4) | 21.1 (5.1) | 0.50 | 1 |
| Asthma | No | 151 (96%) | 202 (94%) | 0.58 | 2 |
| | Yes | 6 (4%) | 12 (6%) | | |
| | Unknown | 77 (49%) | 86 (40%) | | |
| Liver/biliary/pancreatic disease | No | 72 (46%) | 127 (59%) | 0.002 | 3 |
| | Yes | 8 (5%) | 1 (0%) | | |
| | Unknown | 77 (49%) | 86 (40%) | | |
| Immunosuppressant | No | 63 (41%) | 117 (55%) | 0.017 | 2 |
| | Yes | 17 (11%) | 11 (5%) | | |
| | Unknown | 77 (49%) | 86 (40%) | | |
| Steroid use | No | 110 (70%) | 192 (90%) | <0.001 | 2 |
| | Yes | 47 (30%) | 22 (10%) | | |
| Nutritional support | No | 151 (96%) | 210 (98%) | 0.33 | 3 |
| | Yes | 6 (4%) | 4 (2%) | | |
| Transfusion within 48 h of surgery | No | 156 (99%) | 213 (100%) | 1 | 3 |
| | Yes | 2 (1%) | 1 (0%) | | |
| Operative time | [mean (SD)] | 323 (123) | 293 (110) | 0.015 | 1 |
| ASA class | 1: no disturbance | 1 (1%) | 3 (1%) | 0.54 | 3 |
| | 2: mild disturbance | 96 (61%) | 141 (66%) | | |
| | 3: severe disturbance | 60 (38%) | 68 (32%) | | |
| | 4: life threatening | 0 (0%) | 1 (0%) | | |
| Technique | Laparoscopic | 103 (66%) | 89 (42%) | <0.001 | 2 |
| | Open | 54 (34%) | 125 (58%) | | |

1 = t-test, 2 = Chi-square, 3 = Fisher's exact.

* Missing values: BMI = 10,

2.3. Multivariable adjusted outcomes

Odds ratios (ORs) from the multivariable logistic regression model for our primary outcome of any adverse event are shown in Table 3. There were no significant differences in the adjusted odds of any adverse event between early and delayed pouch groups after adjusting for patient characteristics (adjusted OR 0.82, 95% CI 0.43–1.59, $p = 0.55$).

Odds ratios (ORs) from the multivariable logistic regression models for our secondary outcomes of unplanned reoperation and unplanned readmission are shown in Tables 4 and 5. After adjusting for patient characteristics, there were no significant differences in the rate of unplanned reoperations (adjusted OR 0.82, CI 0.41–1.65, $p = 0.57$) or readmission (adjusted OR 0.79, CI 0.47–1.32, $p = 0.36$) for the delayed

pouch group. Without adjusting for patient covariates the length of stay following surgery is estimated to decrease by 17% (OR: 0.83; 95% CI: 0.72–0.97; $p = 0.018$) when a delayed pouch is used instead of an early pouch (Table 6). When age, race/ethnicity, immunosuppressant, steroid use, and technique are accounted for, the estimated decrease falls to 13% (adjusted OR: 0.87; 95% CI: 0.74–1.01; $p = 0.070$) and is no longer significant (Table 6).

3. Discussion

3.1. Summary of results

In our patient population, patients who underwent an early pouch procedure had more comorbidities at the time of pouch creation than delayed pouch patients, including greater rates of steroid and immunosuppressant use. Despite these indicators that these were clinically sicker patients when they underwent IPAA, patients undergoing early pouch procedures were not at an increased risk of either major or minor adverse events. Additionally, patients who had an early pouch procedure did not have higher rates of reoperation or readmission.

3.2. Comparison to previous literature

Although there are little data about early versus late pouch procedures in a pediatric population a similar study was completed in an adult population using National Surgical Quality Improvement Program data [11]. In contrast to our results, Kochar et al. found that in adult patients with UC those undergoing a delayed pouch construction had a lower risk of both minor and major adverse events and a lower risk of unplanned reoperation [11]. This lower risk in the delayed pouch group was not seen in our study, which may be because of baseline differences between adult and pediatric UC populations. While there is concern that pediatric patients with ulcerative colitis have a more aggressive form of UC, they do tend to undergo their IPAA procedures earlier in their disease course and they may have fewer underlying medical

Table 2

Adverse events and length of stay by pouch group.

| Variable ^a | Early (N = 157) | Delayed (N = 214) | P-value | Test |
|--|-----------------|-------------------|---------|------|
| Any adverse event | 26 (16%) | 27 (13%) | 0.36 | 2 |
| Any major event | 14 (9%) | 15 (7%) | 0.63 | 2 |
| Organ space SSI | 4 (3%) | 11 (5%) | 0.32 | 2 |
| Sepsis | 5 (3%) | 6 (3%) | >0.99 | 3 |
| Vent > 48 h | 2 (1%) | 0 (0%) | 0.18 | 3 |
| Length of stay > 30 days | 5 (3%) | 1 (0%) | 0.087 | 3 |
| Death | 1 (1%) | 0 (0%) | 0.42 | 3 |
| Any minor event | 15 (10%) | 15 (7%) | 0.49 | 2 |
| Superficial SSI | 6 (4%) | 4 (2%) | 0.33 | 3 |
| Deep incisional SSI | 2 (1%) | 2 (1%) | >0.99 | 3 |
| Wound disruption | 0 (0%) | 1 (0%) | >0.99 | 3 |
| Bleeding/transfusion | 6 (4%) | 8 (4%) | >0.99 | 2 |
| DVT | 3 (2%) | 1 (0%) | 0.32 | 3 |
| Unanticipated return to OR | 21 (13%) | 23 (11%) | 0.54 | 2 |
| Any readmission | 43 (27%) | 47 (22%) | 0.23 | 2 |
| Surgery to discharge LOS (days) | 7.4 (5.2) | 6.2 (4.1) | 0.030 | 1 |

1 = t-test, 2 = Chi-square, 3 = Fisher's exact.

^a Missing values: vent > 48 h = 1, surgery to discharge LOS (days) = 57.

Table 3
Multivariable analysis of any adverse event by pouch group.

| Analysis | Variable | Level | OR (95% CI) | p-value |
|---------------|-------------------|--------------------|-------------------|---------|
| Univariable | Pouch | Early | Reference | 0.29 |
| | | Delayed | 0.72 (0.41, 1.31) | |
| Multivariable | Pouch | Early | Reference | 0.55 |
| | | Delayed | 0.82 (0.43, 1.59) | |
| | Age (years) | | 1.02 (0.92, 1.13) | 0.72 |
| | | | | |
| | Race/ethnicity | Non-Hispanic white | Reference | 0.002 |
| | | Other/unknown | 2.70 (1.44, 5.10) | |
| | Immunosuppressant | No | Reference | 0.27 |
| | | Yes | 1.76 (0.61, 4.60) | |
| | | Unknown | 0.74 (0.38, 1.41) | |
| | Steroid use | No | Reference | 0.035 |
| | | Yes | 2.19 (1.04, 4.50) | |
| | Technique | Laparoscopic | Reference | 0.49 |
| | | Open | 0.80 (0.42, 1.50) | |

comorbidities than an adult UC population [4,8,9]. This is supported by lower rates of immunosuppressant use prior to surgery in the pediatric early pouch group (14%) compared to the adult group (55%).

In their single-center cohort of 151 pediatric patients undergoing IPAA, Alexander et al. did not find any differences in postoperative complications based on IPAA technique including early vs late pouch creation [23], which is consistent with our analysis. Their cohort experienced a higher deep-organ space infection rate (9%) than was seen in our cohort (4.3%) [23]. Ozdemir et al. similarly report no differences in short term and long term complications between pouch type in their single-center study [24]. Their 30-day wound infection rate (5.5%) is similar to the combined incidence of deep and superficial wound infection seen in our multi-institutional cohort (4.3%).

Before adjusting for patient characteristics, patients in our early pouch cohort did have a longer total length of stay. This is in contrast

Table 4
Multivariable analysis of unplanned reoperation by pouch group.

| Analysis | Variable | Level | OR (95% CI) | p-value |
|------------------------|-------------------|--------------------|-------------------|---------|
| Univariable | Pouch | Early | Reference | 0.44 |
| | | Delayed | 0.78 (0.41, 1.47) | |
| Multivariable analysis | Pouch | Early | Reference | 0.57 |
| | | Delayed | 0.82 (0.41, 1.65) | |
| | Age (years) | | 1.03 (0.93, 1.17) | 0.52 |
| | | | | |
| | Race | Non-Hispanic white | Reference | 0.93 |
| | | Other/unknown | 1.03 (0.48, 2.09) | |
| | Immunosuppressant | No | Reference | 0.87 |
| | | Yes | 0.91 (0.24, 2.69) | |
| | | Unknown | 0.63 (0.31, 1.25) | |
| | Steroid use | No | Reference | 0.075 |
| | | Yes | 1.99 (0.91, 4.20) | |
| | Technique | Laparoscopic | Reference | 0.45 |
| | | Open | 1.29 (0.66, 2.53) | |

Table 5
Multivariable analysis of unplanned readmission by pouch group.

| Analysis | Variable | Level | OR (95% CI) | p-value |
|------------------------|-------------------|--------------------|-------------------|---------|
| Univariable analysis | Pouch | Early | Reference | 0.23 |
| | | Delayed | 0.75 (0.46, 1.20) | |
| Multivariable analysis | Pouch | Early | Reference | 0.36 |
| | | Delayed | 0.79 (0.47, 1.32) | |
| | Age (years) | | 1.06 (0.97, 1.16) | 0.19 |
| | | | | |
| | Race | Non-Hispanic white | Reference | 0.85 |
| | | Other/unknown | 1.05 (0.61, 1.80) | |
| | Immunosuppressant | No | Reference | 0.65 |
| | | Yes | 0.79 (0.27, 2.02) | |
| | | Unknown | 1.08 (0.65, 1.79) | |
| | Steroid use | No | Reference | 0.89 |
| | | Yes | 1.04 (0.55, 1.93) | |
| | Technique | Laparoscopic | Reference | 0.39 |
| | | Open | 0.80 (0.48, 1.32) | |

to the single-center data from Linden et al., which demonstrated that 73% of their early pouch patients had a laparoscopic procedure while only 48% of their delayed pouch patients underwent laparoscopic surgery [25]. They did not complete a subset analysis of length of stay by early vs delayed pouch creation, but they noted no difference in length of stay by open versus laparoscopic operative technique [25]. The postoperative length of stay for both open and laparoscopic procedures in Linden et al. (7 days) was similar to that seen in our cohort for both early (8.4 days) and delayed (6.4 days) pouch creation. Our cohort also reveals high rates of readmission in both the early (27%) and delayed (22%) pouch groups. These high readmission rates are consistent with a prior single center study from Dukleska et al., which demonstrated a readmission rate of 21.5% for pediatric patients undergoing laparoscopic IPAA for both UC and familial adenomatous polyposis [26].

Table 6
Gamma regression of postoperative length of stay by pouch group.

| Analysis | Variable | Level | Multiplicative difference (95% CI) | p-value |
|------------------------|-------------------|--------------------|------------------------------------|---------|
| Univariable analysis | Pouch | Early | Reference | 0.018 |
| | | Delayed | 0.83 (0.72, 0.97) | |
| Multivariable analysis | Pouch | Early | Reference | 0.070 |
| | | Delayed | 0.87 (0.74, 1.01) | |
| | Age (years) | | 1.01 (0.99, 1.03) | 0.39 |
| | | | | |
| | Race | Non-Hispanic white | Reference | 0.63 |
| | | Other/unknown | 0.97 (0.83, 1.13) | |
| | Immunosuppressant | No | Reference | 0.056 |
| | | Yes | 1.29 (1.00, 1.66) | |
| | | Unknown | 0.85 (0.73, 0.99) | |
| | Steroid use | No | Reference | 0.069 |
| | | Yes | 1.18 (0.98, 1.43) | |
| | Technique | Laparoscopic | Reference | 0.30 |
| | | Open | 1.08 (0.93, 1.24) | |

3.3. Implications

The results of this study indicate that even though pediatric patients undergoing a two-stage, early, IPAA are more likely to be on medications, such as immunosuppressants or steroids, that increase their surgical risk they have equivalent outcomes in terms of adverse events as waiting and performing a three-stage, delayed, procedure. These are some of the first pediatric data that can be used to guide surgical decision-making in UC patients rather than relying on physician judgment and training alone. Multicenter collaborative studies are needed to better understand what preoperative factors may be best used for surgical planning. These studies are particularly important to assess clinical factors that may not be well-captured in administrative databases such as preoperative nutritional status, growth retardation and symptom control.

3.4. Limitations

One of the major limitations of this study is that the study population is limited to the 134 hospitals that have elected to join NSQIP-P. Given the commitment involved in joining NSQIP-P it is likely that these are hospitals that already have a significant focus on improving quality of care for surgical patients. It is possible that the results seen here are not reflective of practices and patients treated at hospitals outside of NSQIP-P. This dataset contained a significant number of missing data points that would be valuable to further assess patient comorbidities including preoperative laboratory values and nutritional markers such as weight loss. An additional limitation is that our dataset is limited to complications that occur within 30 days postoperatively and does not include information about long-term outcomes in these patients. Long term functional outcomes in a pediatric population undergoing pelvic surgery such as pouch function, incontinence and concerns such as future fertility are particularly important to quality of life and patient satisfaction [14]. In female patients better understanding of what types of pelvic surgery affect future fertility so as to provide both appropriate treatment and counseling to these young patients is needed and warrants further multicenter studies [27]. While this study provides one evidence-based data point that can be used for surgical decision-making, additional data are needed, particularly about long term patient-centered outcomes such as pouch function. With the data currently collected it is not possible to measure such outcomes using national, administrative databases. Because of the potential for important unmeasured clinical factors in our model as well as the importance of long-term outcomes to patients a larger randomized study with long term follow-up would help further elucidate the true risks and benefits of early versus delayed IPAA.

4. Conclusions

Despite increased comorbidities including increased rates of steroid and immunosuppressant use, patients undergoing an early pouch procedure for ulcerative colitis did not have an increase in odds of a major or minor adverse event. This indicates that despite traditional teaching and data from the adult population that a three-stage procedure is safest for sicker patients at the time of surgery, two-stage procedure is an option that may be considered and deserves further study in the pediatric population.

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