

GASTROENTEROLOGY

Terminal ileum intubation is not associated with colonoscopy quality measuresDavid A Leiman,^{*,†}  Nicole G Jawitz,^{*} Li Lin,[‡] Richard K Wood^{*} and Ziad F Gellad^{*,†,§}^{*}Division of Gastroenterology, [†]Department of Population Health Sciences, Duke University, [‡]Duke Clinical Research Institute and [§]Division of Gastroenterology, Durham VA Health Care System, Durham, North Carolina, USA**Key words**

adenoma detection rate, cancer screening, colonoscopy, health care, quality indicators, terminal ileum intubation.

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Email: david.leiman@duke.edu**Declaration of conflict of interest:** The authors have no relevant conflicts of interest. No writing assistance was used to create this manuscript.**Financial support:** This work was supported in part by VA Career Development Award CDA14-158 (ZFG).**Abstract****Background and Aim:** Intubation of the terminal ileum (TI) demonstrates a complete colonoscopy, but its clinical value during screening exams is unknown. We aimed to determine whether TI intubation during screening colonoscopy is associated with colonoscopy quality measures or identifies subclinical pathology.**Methods:** We performed a retrospective cohort study examining average-risk screening colonoscopies performed at an academic health system between July 2016 and October 2017. Data were extracted from an internal colonoscopy quality registry and the electronic health record. Appropriate statistical tests were used for group comparisons, to correlate TI intubation rate (TIIR) with measures of colonoscopy quality and to examine factors associated with the likelihood of TI intubation.**Results:** There were 7799 colonoscopies performed with adequate prep quality by 28 gastroenterologists. Most patients were female (56.4%) with a median age of 58. The median TIIR was 37.0%, with significant variability among physicians (2–93%). The detection rates for all polyps, adenomas, and sessile serrated polyps were 62.1%, 45.5%, and 7.2%, respectively, and none correlated with TIIR. Intubation of the TI was associated with significantly longer withdrawal times. In a random 10% sample of cases with TI intubation, no clinically significant pathology was found.**Conclusions:** There is wide variability in TIIR among endoscopists. Except to provide photodocumentation of exam extent when other images may be difficult to obtain, the lack of correlation between TI intubation and meaningful clinical outcomes together with the associated time costs suggest routine TI intubation during screening colonoscopy may not be warranted.**Introduction**

Identifying ways to improve measures of colonoscopy quality such as adenoma detection rate (ADR) has gained significant attention.¹ Although recent data suggest ADR is associated with intrinsic endoscopist factors,² coaching and training may improve adenoma detection.³ As a result, a variety of medical devices and endoscopic techniques has been identified as means of positively impacting ADR.^{4,5} Specifically, cecal retroflexion and double ascending colon inspection have been shown to increase adenoma detection.⁶

It is less clear whether other maneuvers associated with increased attention to the ascending colon such as terminal ileum (TI) intubation could also improve ADR. Although prior studies have demonstrated the diagnostic yield of TI intubation in symptomatic patients,^{7,8} it is unlikely to reveal ileal pathology in the context of screening colonoscopy.⁹ Currently, photodocumentation of the TI is recommended in some cases, specifically to demonstrate exam completeness and to satisfy quality measures when other landmarks may be difficult to visualize. Others have suggested regular TI intubation as a means to maintain endoscopist's skill despite the lack of guideline direction.¹⁰

Whether TI intubation is associated with traditional measures of colonoscopy quality such as ADR, however, is unknown. It may be that the time spent in the proximal colon deflecting folds during attempts at TI intubation may reveal previously unnoticed polyps, thereby boosting one's quality measure performance. Additionally, those endoscopists who frequently intubate the TI may be demonstrating overall higher performance that likewise could be associated with adenoma or sessile serrated polyp detection.

We therefore aimed to examine the value of TI intubation by exploring its clinical diagnostic yield and association with traditional measures of colonoscopy quality against perceived costs, including time required to perform TI intubation during average-risk screening colonoscopy.

Methods

We performed a retrospective cohort study examining all ambulatory colonoscopies performed at a single academic health system between July 2016 and October 2017. The cohort was restricted to average-risk screening colonoscopies with adequate bowel

preparation, defined as the ability to follow recommended surveillance guidelines.¹¹ Patients were excluded if they had inadequate prep or underwent more than one colonoscopy during the study period. Physicians were excluded if they had fewer than 50 eligible colonoscopies performed during the study period or had incomplete quality measure data entry on a procedure.

Physicians at our institution routinely document relevant clinical information for quality improvement and quality assurance purposes using discrete data elements within the electronic health record (EPIC systems, Verona, WI). These data include procedural indication and date of last colonoscopy from the history and physical as well as relevant procedural findings in the postprocedure note, such as extent of colonoscopy, adequacy of bowel prep, specimen collection, and follow-up interval recommendations. After pathology is returned and reviewed, a letter is sent to the patient with histologic findings and final follow-up recommendations.

Utilizing this quality assurance system, we collected information on terminal ileum intubation rates (TIIR), adenoma detection rate (ADR), sessile serrated polyp detection rates (SSPDR), and total polyp detection rates (PDR). In order to evaluate the yield of small bowel inspection, and because discrete data elements do not exist for small bowel pathology on colonoscopy result letters, a 10% random sample of procedures were identified and manual chart review was performed to identify frequency of rate of biopsy, abnormal pathology, and ultimate diagnostic yield.

Additional procedural details were collected from routinely available clinical data through electronic data abstraction. Sedation type, procedure site, time of day, and procedure timing (scope insertion, cecal intubation, and scope withdrawal times) were recorded. Sedation was dichotomized as moderate sedation or monitored anesthesia care. Time of day was categorized as morning (8–11 AM), midday (11 AM–2 PM), and afternoon (after 2 PM).

We also collected both physician and patient level demographic data. Endoscopists' age, sex, years in practice, and primary specialty were recorded using health system records. Patients' age, sex, race, body mass index (BMI), and smoking and alcohol use histories were obtained through an electronic query of the corporate data warehouse.¹² Self-reported current or prior smoking history independent of pack years was considered positive smoking history and, likewise, any self-reported alcohol use was considered positive alcohol exposure independent of frequency or volume.

All data were analyzed using SAS software (Version 9 for Linux, SAS Institute Inc., Cary, NC, USA). Descriptive statistics, including frequencies or median with interquartile range, were calculated to describe the demographic and clinical characteristics. Wilcoxon rank sum and χ^2 tests were used for group comparisons. Pearson correlation coefficient was used to assess how PDR, ADR, and SSPDR detection correlated with TIIR. A two-level generalized linear mixed regression model was used to examine whether patients' characteristics, colonoscopy procedure characteristics, and endoscopist characteristics would be associated with the likelihood of TI intubation during colonoscopy screening. Level 1 variables included patient's sex, race, age, BMI, tobacco use, and alcohol use as well as type of anesthesia used in procedure, procedure time of the day, insertion time, and withdrawal time. Level 2 variables included endoscopist's sex, age, primary specialty, and years in practice. A random intercept was added to model at Level 2 to

account for an endoscopist's clustering effect. The Duke University Medical Center institutional review board approved this study.

Results

Cohort characteristics. A total of 7799 average-risk screening colonoscopies with adequate prep quality were performed by 28 endoscopists during the study period (Fig. 1). A total of five sites were included in the analysis, including two ambulatory surgery centers and three hospital-based units. Cases were most frequently performed ($n = 4950$, 63.5%) at the ambulatory surgery centers. The median age of patients was 58 (Table 1).

All endoscopists completed gastroenterology fellowship, and most ($n = 24$, 85.7%) identified gastroenterology rather than hepatology as their primary specialty. The median age of endoscopists was 40, most ($n = 19$, 67.9%) were men and had a median annual volume of 297 average-risk screening colonoscopies and a median of 8 years of experience.

Clinical outcome measures. There were 3356 (43%) cases in which the TI was intubated, while the median rate of TI intubation was 37.0%, with a range from 2% to 93% (Fig. 2). Given the wide variability in TIIR, we conducted an analysis to evaluate factors associated with TI intubation using two-level generalized linear mixed regression. With all the patient (age, sex, race, BMI, smoking history, and alcohol use), physician (age, sex, years in practice, and primary specialty), and procedural factors (sedation type, procedure time of day, insertion,

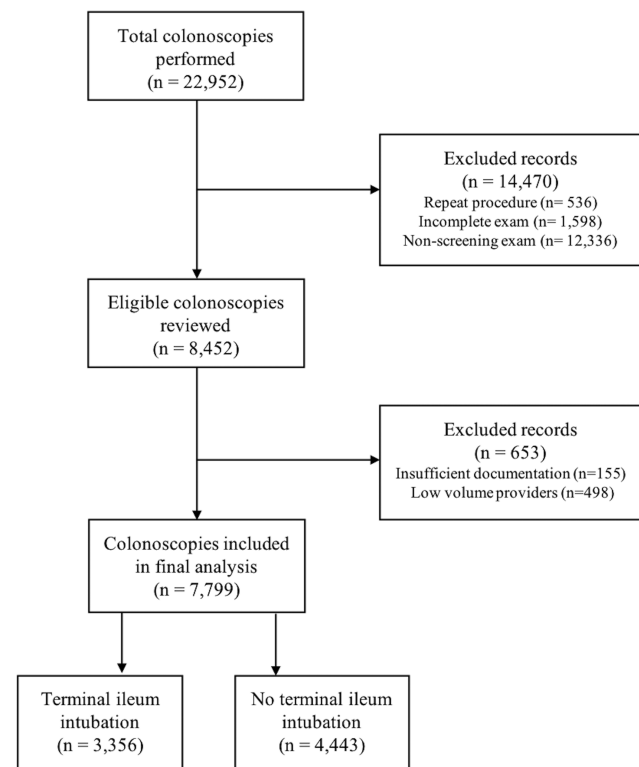


Figure 1 Study flow diagram.

Table 1 Patient and procedural characteristics by terminal ileum intubation

Patients (<i>n</i> = 7799) [†]	Overall (<i>N</i> = 7799)	TI (<i>N</i> = 3356)	No TI (<i>N</i> = 4443)
Age, median (IQR), years	58 (52–64)	57 (51–63)	59 (52–65)
Men	3388 (43.6%)	1448 (43.3%)	1940 (43.7%)
Race			
White	4588 (60.3%)	2018 (61.9%)	2570 (59.1%)
Black	2449 (32.2%)	939 (28.8%)	1510 (34.7%)
Other	571 (7.5%)	303 (9.3%)	268 (6.2%)
BMI, median (IQR)	29 (25.4–33.5)	28.5 (25.1–32.9)	29.4 (25.7–34.1)
Tobacco Use	678 (8.7%)	267 (8.0%)	411 (9.3%)
Alcohol Use	4367 (56.6%)	1913 (57.8%)	2454 (55.7%)
Procedural characteristics [‡]			
Moderate sedation	4210 (76.1%)	2005 (85.3%)	2205 (69.4%)
Morning (8–11 AM)	2472 (41.0%)	1068 (41.6%)	1404 (40.7%)

BMI, body mass index; IQR, interquartile range; TI, terminal ileum.

[†]22–25% data were missing.

[‡]0.3–7% data were missing.

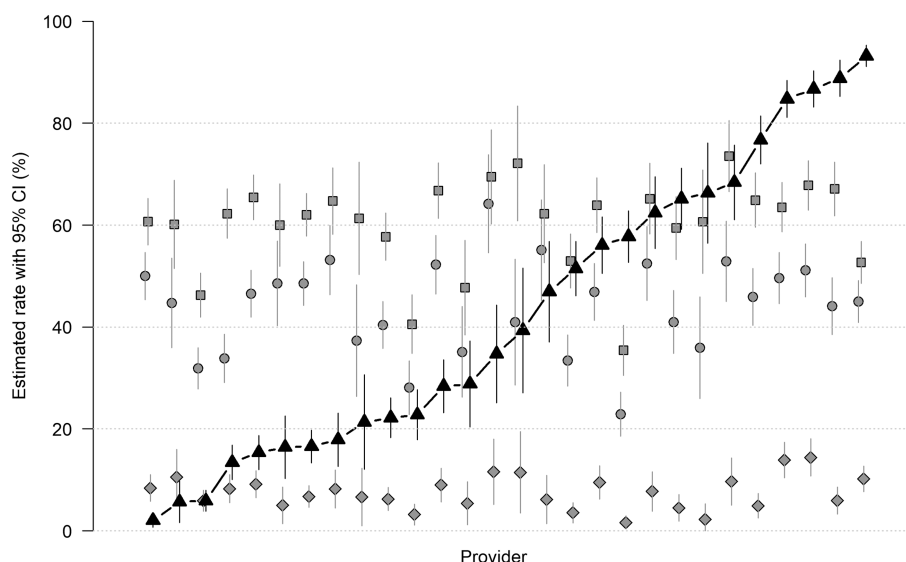


Figure 2 Colonoscopy quality measures and terminal ileum (TI) intubation rate by physician. There is wide variability in the rate of TI intubation. This maneuver is not associated with meaningful clinical outcomes such as total polyp detection and sessile serrated polyp detection rates. Important colonoscopy quality measures such as adenoma detection rate (ADR) are also not correlated with TI intubation rates. —■—, polyp detection rate (PDR); —●—, Adenoma detection rate (ADR); —◆—, Sessile serrated polyp detection rate (SSPDR); —▲—, TI intubation rate (TIIR).

and withdrawal times) included in the model, only BMI ($P = 0.0003$), insertion time ($P < 0.0001$), and withdrawal time ($P = 0.04$) were significantly associated with TI intubation (Table 2). For every unit increase in BMI, the odds of TI intubation were 4% lower. For each additional minute of insertion and withdrawal, the odds of TI intubation decreased by 7% and 3%, respectively.

The median PDR, ADR, and SSPDR across all endoscopists were 62.1%, 45.5%, and 7.2%, respectively. There was no significant differences in the PDR, ADR, or SSPDR in cases with or without TI intubation (Table 3). We found PDR was strongly correlated with both ADR ($r = .68$, $P < 0.0001$) and SSPDR ($r = .63$, $P = 0.0004$). Also, ADR is moderately correlated with SSPDR ($r = .58$, $P = 0.001$). When evaluating the relationship between

TIIR and these polyp detection rates, neither PDR, ADR, nor SSPDR were correlated with TIIR (Table 4).

We also evaluated the diagnostic yield for incidental findings of clinical importance in the terminal ileum. Unlike colon polyp pathology, we do not collect small bowel pathology as a structured data element. Therefore, we generated a random sample of all cases with TI intubation ($n = 354$, 10.5%) to determine whether it was associated with any relevant findings and performed manual chart review of these cases. Visual abnormalities warranting biopsies were noted in four cases (1%). Pathology revealed lymphoid hyperplasia in one patient, normal small bowel mucosa in one patient, and acute enteritis without chronic changes in two patients that was attributed to medication usage and did not require additional testing.

Table 2 Factors associated with terminal ileum intubation

	Odds ratio	95% confidence interval	<i>P</i> value
Physician factors			
Age	1.14	0.84–1.54	0.41
Sex			0.96
Male	Referent		
Female	0.96	0.23–4.02	
Primary specialty			0.80
Luminal GI	Referent		
Hepatology	0.78	0.11–5.46	
Years in practice	0.91	0.68–1.21	0.50
Patient factors			
Age	0.99	0.97–1.01	0.18
Sex			0.32
Male	0.88	0.68–1.14	
Female	Referent		
Patient race			0.30
Black	Referent		
White	1.07	0.80–1.42	
Other	1.47	0.90–2.40	
BMI	0.96	0.94–0.98	0.0003
Tobacco use	0.81	0.49–1.36	0.43
Alcohol use	0.84	0.65–1.08	0.17
Procedural factors			
Anesthesia type			0.62
Anesthesia	Referent		
Moderate Sedation	0.91	0.63–1.31	
Time of day			0.20
Morning (8–11 AM)	1.23	0.95–1.59	
Midday (11 AM–2 PM)	Referent		
Afternoon (after 2 PM)	0.90	0.57–1.42	
Insertion time	0.93	0.90–0.95	<0.0001
Withdrawal time	0.97	0.94–1.00	0.04

Time costs assessment. We performed an evaluation of the time associated with TI intubation (Table 3). In order to adjust for potential bias in this assessment, we only analyzed cases without polyp removal or biopsies. The cecal intubation time was significantly shorter in cases with TI intubation compared with those without (median and interquartile range: 6 [4, 10] vs 5 [4, 8]; $P < 0.0001$). Although the withdrawal times were significantly

longer (median and interquartile range: 9 [7, 12] vs 11 [8, 13]; $P < 0.0001$) when the TI was intubated, more than 75% of the cases had a withdrawal time greater than 8 min in both those with and without TI intubation. The total procedure time did not vary based on TI intubation.

Discussion

Intubation of the TI is a marker of completeness of an exam,¹³ though the data to support regular TI intubation during screening colonoscopy is lacking. In our study of average-risk screening colonoscopies, we found that TI intubation is associated with significantly longer withdrawal times without the benefit of increased adenoma or sessile serrated adenoma detection rates. In the absence of guideline recommendations, there is wide variability in practice patterns with only shorter insertion times and lower patient BMI predictive of TI intubation.

Several prior studies have evaluated the utility of TI intubation in a variety of settings, with potential benefits ranging from confirmation of complete colonoscopy to identifying small bowel pathology.^{14–17} However, most such studies were conducted more than 10 years ago and none previously evaluated successful TI intubation in relation to colonoscopy quality measures. Meanwhile, it has been suggested that the process of attempting TI intubation may deflect folds and uncover previously hidden lesions,¹⁸ which might be particularly important given that colonoscopy is less effective at preventing right-sided cancers than those on the left.^{19–22} Also, it has been shown that increased attention to the right colon through either cecal retroflexion or double ascending colon examination can increase ADR.²³ We therefore aimed to determine whether the practice of TI intubation during screening colonoscopy was associated with increased polyp detection rates.

We found that total PDR and ADR were not significantly different whether the TI was intubated or not. We also evaluated whether this might affect detection of sessile serrated polyps and found no significant correlation between SSPDR and TIIR. Importantly, to minimize the potential bias and yield, we restricted our analysis to only average-risk screening colonoscopies in which the prep quality was adequate to follow surveillance guidelines. While we did not stratify based on whether the screening colonoscopy was an index versus average-risk follow-up screening exam, age was not associated with TI intubation in our model. Also, the median age of patients was 58, suggesting that most included

Table 3 Terminal ileum intubation impact on colonoscopy quality measures

	Total	No TI intubation (<i>n</i> = 4443)	TI intubation (<i>n</i> = 3356)	<i>P</i> value
Polyp detection rate [†]	58.9 (57.8, 60.0)	58.1 (56.7, 59.6)	59.9 (58.2, 61.6)	0.11
Adenoma detection rate [†]	43.1 (42.0, 44.2)	43.2 (41.7, 44.6)	43.1 (41.4, 44.8)	0.98
Sessile serrated polyp detection rate [†]	7.6 (7.0, 8.2)	7.2 (6.4, 8.0)	8.1 (7.2, 9.0)	0.14
Cecal intubation (minutes) [‡]	6 (4, 9)	6 (4, 10)	5 (4, 8)	<0.0001
Withdrawal (minutes) [‡]	10 (8, 12)	9 (7, 12)	11 (8, 13)	<0.0001
Total procedure (minutes) [‡]	16 (13, 20)	16 (12, 21)	16 (13, 20)	0.37

Procedural times were analyzed only in colonoscopies during which no polypectomy was performed, where No TI intubation *n* = 1861 and TI intubation *n* = 1346.

TI, terminal ileum.

[†]%, (95% confidence interval).

[‡]Median (interquartile range).

Table 4 Correlation between colonoscopy metrics and terminal ileum intubation rates

	Polyp detection rate	Adenoma detection rate	Sessile serrated polyp detection rate	Terminal ileum intubation rate
Polyp detection rate	1	0.68 ($P < 0.0001$)	0.63 ($P = 0.0004$)	0.24 ($P = 0.2$)
	Adenoma detection rate	1	0.58 ($P = 0.001$)	0.11 ($P = 0.6$)
		Sessile serrated polyp detection rate	1	0.02 ($P = 0.9$)
			Terminal ileum intubation rate	1

Pearson correlation coefficient, r (P value).

patients were likely undergoing first time colorectal cancer screening examination.

The overall ADR among included physicians in our study was high as well, but one achieved the current blended ADR quality target of 25%.²⁴ This could account for the inability to detect a significant association between ADR and TI intubation, as those providers with the lowest baseline ADR likely have the highest chance of improvement with current techniques. It is also probable that the highest potential for increasing polyp detection in the context of TI intubation would be in detecting right-sided lesions. Our quality assurance database does not track colon location for polyps, and many providers' practice is to combine polyps from multiple sites into a single, or limited number of, pathology containers. Although we could not account for all factors known to increase adenoma risk or provide protective effects such as physical activity²⁵ or aspirin use,²⁶ our data were obtained in an observational real-world fashion across multiple sites and are likely to be representative of the general population. Together, these are important areas for future study.

Likewise, our study affirms the low likelihood of discovering incidental ileal pathology, with a diagnostic yield of 0% within a random sample of our overall cases. Although others have reported significant pathology rates of 20% or 40% in the setting of chronic diarrhea or suspected inflammatory bowel disease,²⁷ the rates in asymptomatic or noninflammatory bowel disease patient is low and ranges from 0.3% to 2.6%.^{13,28,29} Similar to our findings, within a cohort undergoing screening colonoscopy, the rate of TI pathology was 0.07%.⁹ As a result, even in cases in which TI visualization is performed to confirm exam extent during screening colonoscopy, guidelines recommend against obtaining confirmatory small bowel pathology.³⁰

Despite the trivial risk of missing pathology within the TI, there remains significant variability in frequency of TI intubation. Previously published studies describing TIIR among their cohorts describe rates that vary from 16% to 95%.^{13,28,29,31–33} Although these studies differ substantially with respect to their protocols and motivation for TI intubation, in the absence of guideline direction, we found the average rate of TI intubation in general practice was 37% among 28 physicians and ranged from 2% to 93%. The median rate among the included endoscopists is higher than a prior study evaluating factors associated with TI intubation, although in that retrospective database analysis, academic center location had significantly higher TIIR compared with VA and community sites.³⁴ In contrast to their findings, we did not

identify patient sex, race, or age as important factors predicting TI intubation.

In our two-level generalized linear mixed regression model, patient BMI, insertion, and withdrawal times were the only significant factors associated with TI intubation. Although this suggests that physicians were more likely to perform TI intubation in procedures that were technically less challenging, we cannot conclude that from our data. Further, although there was a significant association in our study between BMI and TI intubation, the overall effect was small with each increasing unit of BMI leading to a 4% reduction in TI intubation. This could possibly relate to other technical issues with TI intubation. For example, the ileocecal valve is a notable location for submucosal fat deposition that could be associated with BMI and ileocecal valve morphology.³⁵ Along with patient posture, BMI has also been shown to affect TI intubation,³⁶ whereas prior studies have not shown an association between BMI and cecal intubation times.³⁷

To reduce the influence of polyp removal on procedural times, we only evaluated times for procedures in which no polypectomy or biopsies were attempted. While we do not routinely collect data on fellow participation as part of our quality assurance program, given the overall large procedural volume and fact that the location for most colonoscopies was at an ambulatory surgery center where fellows rarely practice, it is expected that fellow involvement would have limited influence on overall results. Additionally, the average withdrawal times in both those with and without TI intubation were above target goals of at least 6 min.²⁴ Nonetheless, in cases with TI intubation, the withdrawal times were significantly longer. Although this cannot be definitively concluded from the available data, this extra procedural time is possibly because of the time spent intubating and evaluating the TI, which ultimately had no additional yield. These findings are consistent with guideline acknowledgments that intubation of the ileum takes additional effort and time.³⁰ From a practical standpoint, any time saved by easier cecal intubation during screening colonoscopy could be used to focus on polyp detection rather than TI intubation, unless it is for purposes of documenting exam extent.

In conclusion, in a large quality assurance database, TI intubation was associated with significantly increased withdrawal times without any correlated increase in detection of adenomas, sessile serrated polyps, or small bowel pathology. There is wide variation in TIIRs across endoscopists, but there is no detected benefit with respect to meaningful colonoscopy outcome measures. Except in situations needed to provide photodocumentation of exam extent,

the practice of routine TI intubation may not be warranted as part of routine screening colonoscopy.

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