Diagnostic Yield Variation with Colonoscopy among Pediatric Endoscopists

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Keywords

Ileal intubation · Colonoscopy · Provider variation · Diagnostic yield

Abstract

Background: The primary aim of our study was to determine provider variation in diagnostic yield in a pediatric endoscopy center. Secondary aims were to examine ileal intubation rates as well as procedural complications at the provider level. **Methods:** A retrospective review of sequential pediatric patients who underwent a colonoscopy, completed by June 2018, determined the rates of endoscopically abnormal (EA) and isolated histologically abnormal (IHA) colonoscopies; the overall diagnostic yield was the combination of EA and IHA. **Results:** In total, 374 charts were reviewed. This study found high variability in diagnostic yield among the 16 clinicians ranging from as low as 22% to as high as 86% ($p = 0.11$) with an overall diagnostic yield of 48% for colonoscopy; excluding follow-up colonoscopies, the diagnostic yield was 42%. Abnormal calprotectin and abnormal blood tests were associated with higher diagnostic yields of 83 and 65%, respectively, compared with symptoms such as abdominal pain, diarrhea, and rectal bleeding which had yields of 39, 43, and 61%. Ileal intubation rates averaged 90% (range 63–100%, $p = 0.06$). In patients with a normal colon, there were 21 (6%) patients with an EA ileum and an additional 16 (4%) with an IHA ileum. Prep quality was rated excellent, good, or average in 97%. In addition, there was a low rate of

serious complications (1 of 374). **Conclusions:** This study highlights the individual variability in diagnostic yield and ileal intubation rates in a pediatric gastroenterology practice. Goals for pediatric endoscopy could include ileal intubation rates of >90% and provider diagnostic yields of >40%.

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Introduction

With pediatric gastroenterology endoscopic procedures, there are little data regarding variability in provider performance with regard to diagnostic yield [1–4]. A recent NASPGHAN clinical report [3] sought to provide parameters for quality improvement in pediatric endoscopy. “A high-quality endoscopy has been defined as an examination in which patients receive an indicated procedure, correct and relevant diagnoses are recognized or excluded, any therapy provided is appropriate, and all steps that minimize risk have been taken.” Specific measures include patient education, timeliness, bowel preparation, ileal intubation, adverse events, and patient satisfaction.

In clinical practice, there is wide variation in indications for colonoscopy and the frequency of colonoscopy per provider. Careful selection of patients can help improve diagnostic yield and minimize the risk of low value procedures. A normal colonoscopy has not been shown to improve outcomes in children with functional gastrointestinal diseases [5].

As part of our efforts in establishing quality metrics in our outpatient endoscopy center, we aimed to identify the variation in diagnostic yield among the 16 clinicians in our pediatric private practice group. Secondary aims were to examine ileal intubation rates as well as procedural complications at the provider level.

Our goal is for every pediatric patient to have a high-quality endoscopy designated by a good indication for the procedure, good technique, and appropriate follow-up. Even though diagnostic yield is not used as a quality metric [1–3], it is likely important as a measure of high value care. This single-center retrospective chart review of an ambulatory pediatric endoscopy center cohort sought to determine the provider variation in diagnostic yield.

Methods

After obtaining approval from our Institutional Review Board, we performed a retrospective chart review of sequential pediatric patients who underwent a colonoscopy at our outpatient pediatric endoscopy center. Specifically, for each of 16 clinicians, we attempted to identify the most recent 25 charts of patients who had a colonoscopy. Charts were selected by review of the ambulatory center's schedule. All procedures were completed prior to June 2018.

In total, 374 charts were reviewed instead of 400. This was due to several factors. The decision to identify 25 charts was based on the goal of identifying a similar number of patients in each of the 16 providers at the ambulatory center. Two physicians had completed only 22 colonoscopies at the time of this review; one because of joining the group in the preceding year and one due to less frequent use of colonoscopy over approximately 3 years. After review, there were several charts pulled in which patients did not have a colonoscopy; these were misclassified in the scheduling system.

Prep quality in this study was a subjective assessment by the endoscopist as determined by the operative report. All patients received the same prep instructions which included polyethylene glycol followed by a sodium phosphate enema; the latter could be skipped if stools were clear.

After obtaining demographic information, each chart was examined for indications, number of office visits before colonoscopy, testing prior to procedure, and treatments prior to colonoscopy. Blood tests and stool calprotectin were considered abnormal based on the performing commercial laboratory. Other variables that were reviewed included whether this was an isolated colonoscopy or a colonoscopy-esophagogastroduodenoscopy (EGD; panendoscopy), whether the procedure was a first procedure or a follow-up, pathology results, and complications following procedure. With regard to complications, each chart was reviewed to determine if there were any emergency room visits, hospitalizations, or office visits within a week following the procedure.

With regard to indications, the term "isolated abdominal pain" was used when no other major indications, such as weight loss, diarrhea, or rectal bleeding, were present. Some patients with isolated abdominal pain had a family history of inflammatory bowel disease (IBD). Due to the variability of documentation of family history, this factor was not specifically identified.

Abnormal histology was determined by review of the pathology report. Each pathology report was generated from one of 2 pathologists.

When reviewing charts for diagnostic yield, we considered the finding of gross abnormalities in the appearance of the mucosa as endoscopically abnormal (EA) and in those with normal mucosa but abnormal pathology as isolated histologically abnormal (IHA). The focus on EA was based on several factors. For IBD, the Paris classification relies on gross findings to establish extent of disease [6]. In addition, vague nonspecific pathologic findings are frequently evident and often irrelevant, particularly with EGD. Several trivial findings including lymphoid hyperplasia, internal hemorrhoids, and pinworms were not considered EA.

Statistics Information

All statistical analyses were conducted using SAS 9.4 (Cary, NC, USA). Descriptive statistics using medians and interquartile ranges for continuous variables or counts and frequencies for categorical variables were analyzed. Continuous data were compared using Wilcoxon rank-sum tests and categorical variables were compared using chi-square or Fisher's exact tests (for cell counts <5). Variability between all 16 providers in normal colonoscopy yield, whether the ileum was reached, and type of procedure used (colonoscopy vs. combined with EGD) was assessed using generalized linear mixed models with a subject-specific random intercept for providers. Z-tests from the modeled random intercepts were used to determine the presence of significant variability between providers. Statistical significance for all hypothesis testing was determined at the 0.05 level using two-tailed *p* values.

Results

Patient Characteristics

In total, 374 colonoscopies completed by 16 pediatric gastroenterologists were reviewed. The demographics and characteristics are detailed in Table 1. Most patients (*n* = 318, 85%) who underwent a colonoscopy underwent a combination procedure with EGD; 56 (15%) patients underwent an isolated colonoscopy. All patients received general anesthesia with propofol administered by an anesthesiologist.

Workup

The majority of patients underwent testing prior to endoscopy. Three hundred thirteen (84%) patients had blood tests obtained, and 159 (43%) patients had a stool calprotectin. Among those with testing, 86 (28%) had an abnormality in blood, and 73 (46%) had an abnormal stool calprotectin. There were 45 patients with an abnormal calprotectin and normal blood tests. In addition, 145 (39%) had stool tests done to evaluate for stool pathogens; the frequency of stool pathogen testing is identical to the frequency of patients with diarrhea as an indication for colonoscopy (Table 2).

Table 1. Overall summary characteristics, *n* = 374 patients

Patient demographics	All, <i>n</i> (%)
Gender	
Male	171 (45.7)
Female	203 (54.3)
Patient age, years, median (25th–75th)	14 (11–17)
Time from 1st office visit until procedure date, weeks	
<2	58 (15.5)
2–4	74 (19.8)
4–8	71 (19.0)
8–16	38 (10.2)
16–52	36 (9.6)
>52	97 (25.9)
Procedure	
Colonoscopy only	56 (15.0)
EGD – colonoscopy	318 (85.0)
1st or follow-up colonoscopy	
1st	302 (80.8)
Follow-up	72 (19.2)
<i>Workup prior to endoscopy</i>	
Hemoglobin	
Low	53 (14)
Normal	258 (69)
Not ordered	63 (17)
Sedimentation rate	
Elevated	38 (10)
Normal	214 (57)
Not ordered	122 (33)
Albumin	
Low	18 (5)
Normal	270 (72)
Not ordered	86 (23)
C-reactive protein	
High	36 (10)
Normal	223 (60)
Not ordered	115 (30)
Any abnormal blood test	
Abnormal	86 (23)
All normal	227 (61)
Not ordered	61 (16)
Stool calprotectin	
Elevated	73 (20)
Normal	86 (23)
Not ordered	215 (57)
Prep quality	
Excellent	83 (22.3)
Good	230 (61.8)
Adequate	47 (12.6)
Poor	12 (3.2)
EGD, esophagogastroduodenoscopy.	

Prep Quality

Overall, clinicians encountered a poor prep in only 12 (3%) colonoscopies; the prep was considered excellent in 83 (22%), good in 230 (62%), and adequate in 47 (13%; Table 1).

Table 2. Indications for procedure, *n* = 374 patients

Indications (not mutually exclusive)	Number (%)
Rectal bleeding	95 (25)
Abdominal pain (including isolated abdominal pain) ¹	258 (69)
Isolated abdominal pain only ¹	46 (12)
Weight loss/poor growth	75 (20)
Diarrhea	145 (39)
Abnormal blood test (ESR, CRP, albumin, hemoglobin) ²	86 (23)
Abnormal calprotectin ³	73 (20)
Abnormal calprotectin and normal blood labs ⁴	38 (10)
Follow-up IBD	33 (9)
Other ⁵	18 (5)

¹ Isolated abdominal pain: abdominal pain without presence of abnormal blood lab, rectal bleeding, diarrhea, or weight loss/poor growth.

² *n* = 61 not tested for any blood test: ESR, CRP, albumin, or hemoglobin.

³ *n* = 215 not tested for calprotectin.

⁴ *n* = 226 did not have tests for calprotectin and blood test.

⁵ Other includes: congenital hypertrophy of retinal pigment epithelium (CHRPE), and abnormal imaging.

IBD, inflammatory bowel disease; ESR, erythrocyte sedimentation rate; CRP, C-reactive protein.

Indications

In the majority of patients, there were a combination of indications for the colonoscopy (Table 2). While abdominal pain was present in 258 (69%) of patients who underwent colonoscopy, only 12% had isolated abdominal pain without another major indication.

Diagnostic Yield

There was considerable variability of diagnostic yield among clinicians, though it did not reach statistical significance (*p* = 0.11). As evident in Figure 1, diagnostic yield (combined EA and IHA) was as low as 22% to as high as 86% with an overall diagnostic yield of 48% for colonoscopy; the median value for diagnostic yield was also 48%. When excluding the follow-up cases, the average diagnostic yield was 42%.

Among patients with abnormal laboratory values, the diagnostic yield was higher than for those with other indications based on symptoms (Fig. 2). In those with abnormal blood tests, the colonoscopy results were EA in 56 of 93 (60%) and IHA in an additional 5 (5%). In those with an abnormal stool calprotectin, 53 (73%) had an EA colonoscopy and an additional 7 (10%) had an IHA colonoscopy.

The symptom with the highest diagnostic yield, when combining both EA and IHA, was rectal bleeding at 61% (Fig. 2). In comparison, diagnostic yield for abdominal pain was 39%, weight loss was 45%, and diarrhea was 43%. Isolated abdominal pain, which indicated that none

Fig. 1. Colonoscopy diagnostic yield by doctor. The diagnostic yield for colonoscopy varied considerably among the 16 individual physicians. The diagnostic yield was a summary of both EA and IHA. EA, endoscopically abnormal; IHA, isolated histologically abnormal.

of the other major indicators were present, yielded a diagnostic yield of 24%.

Isolated Colonoscopy Compared to Panendoscopy

As noted in Figure 3, there was variability among clinicians in the frequency of isolated colonoscopy procedure usage, from 0 to 42%. The frequency of having a normal procedure was significantly more common among patients who underwent a panendoscopy procedure compared to patients who underwent an isolated colonoscopy (Table 3). Normal endoscopic appearance of colon and ileum was approximately twice as common in patients undergoing a panendoscopy (60%) compared with isolated colonoscopy (27%). Similarly, when combining gross appearance and histology among patients with panendoscopy, 53% were normal compared with 26% of isolated colonoscopy patients.

Ileal Intubation

The success rate of ileal intubation ranged from 63 to 100% with a group average of 90% (Fig. 4); the differences in the rate of ileal intubation did not reach statistical significance ($p = 0.06$). Furthermore, there was not a correlation between ileal intubation rate and clinician experience;

however, all physicians in the study had a minimum of 5 years of clinical experience after fellowship.

It is worth noting that some physicians may elect to forego ileal intubation in patients with colonic polyps; though, this effect on ileal intubation is unclear. In our cohort, polyps were present in 27 patients (7%). Two of the clinicians who achieved a 100% intubation rate both had 2 patients with polyps.

One reason why ileal intubation is important is related to the diagnostic yields. Among patients with a normal colon, there were 21 (6.4%) patients with an EA ileum in this cohort and an additional 16 (4.3%) with an IHA ileum. Thus, in total, 10.7% of the diagnostic yield of the colonoscopy was exclusively from the ileum. Also, we examined the charts of the 16 patients with IHA of the ileum; 6 of these patients had a prior diagnosis of IBD. After at least 1 year of follow-up in all cases, only 1 patient of the remaining 10 patients was determined to have a new diagnosis of IBD; the others were thought to have functional bowel disease.

EGD Findings

In patients who had panendoscopy, the findings from the EGD were reviewed and are summarized in Table 3. While a grossly normal EGD was identified in 59%, only

Fig. 2. Colonoscopy yield by indication. The diagnostic yield for colonoscopy varied considerably based on the indication. Findings were classified as either EA based on gross abnormalities in the appearance of the mucosa or as IHA. EA, endoscopically abnormal; IHA, isolated histologically abnormal.

29% were considered to have normal histology and normal appearance. Overall, it is noted that EGDs are performed much more frequently than colonoscopies in our patient population. From January 1, 2018, through December 31, 2018, our outpatient center had 1968 EGDs and 780 colonoscopies.

Safety

The safety of isolated colonoscopy and panendoscopy was excellent in this cohort. Only 1 patient had a significant complication. This patient had bleeding that began a few hours after a polypectomy; this resulted in a hospital admission, blood transfusion, and repeat colonoscopy for control of bleeding.

Discussion

This retrospective review of an ambulatory pediatric gastroenterology private practice identified high variability in diagnostic yield among the 16 clinicians

ranging from as low as 22% to as high as 86% with an overall diagnostic yield of 48% for colonoscopy; the diagnostic yield was 42% when excluding follow-up cases. In addition, there was high variability in ileal intubation rates with an average of 90% (range 63–100%) and a low rate of serious complications (1 of 374).

To our knowledge, variability by individual physicians in diagnostic yield and ileal intubation rate has not been reported in a large pediatric population previously. It is notable that our overall diagnostic yield of 48% is similar with other studies [7–13]. Manfredi et al. [8] examined 390 colonoscopies performed by 26 different clinicians. Abnormal gross findings were present in 218 (56%), whereas 50% had abnormal pathology. In other pediatric studies, the diagnostic yields for colonoscopy ranged from 33 to 64% [9, 10, 13–15].

It is worthwhile to speculate about why there is so much variation in diagnostic yield among clinicians in our practice. Certainly, some variation could be accounted for by differences in patient encounters and some variation could be due to chance related to sample size.

Fig. 3. Variation among physicians in using isolated colonoscopy compared with panendoscopy. This figure shows the frequent variation among 16 individual physicians in the use of isolated colonoscopy or panendoscopy. Overall, only 15% of patients undergoing a colonoscopy had an isolated colonoscopy and 85% had a panendoscopy.

Some physicians, based on their interests and reputations, may have subtle differences in the likelihood of organic disease in their individual patient populations. When examining the individual physicians in our study with the highest and lowest yield, there was not a unique patient population; that is, neither physician had a specialized focus in IBD nor functional bowel disease. Thus, it is more likely that the driving factor for the variation in diagnostic yield is related to the threshold for performing an endoscopy in patients with probable functional disorders. In addition, some physicians may be more likely to recommend a colonoscopy for isolated rectal bleeding and some may be more likely to start with laxative therapy. For all of these decisions, the role of parental pressures or physician attitudes cannot be discerned in a retrospective study.

While a negative endoscopic study has not been shown to improve outcomes in patients with functional abdominal pain [5], it is likely that a normal colonoscopy would provide significant reassurance in some specific circumstances including in familial polyposis and in patients at high risk for IBD.

Since the diagnostic yield in our cohort was lower for panendoscopy compared with for isolated colonoscopy, this is likely related to increased selection of panendoscopy in children with functional disorders. In addition, the indications of rectal bleeding and follow-up IBD which had higher diagnostic yield rates than other indications were more likely to result in an isolated colonoscopy.

Our group's average ileal intubation rate of 90% compares favorably with other studies which have ranged from 52 to 100% [7, 9, 10, 13, 16–18]. The pediatric study reporting a 100% ileal intubation rate involved 6 endoscopists who had >10 years of experience (mean 19 years) and more than a thousand prior colonoscopies each [13]. The NASGPHAN clinical report on quality improvement in pediatric endoscopy suggests an ileal intubation goal of 90% as a general quality metric [3], though noting that this is often not achieved. Our study shows why ileal intubation is important. In our cohort, among patients with a normal colon, there were 21 (6%) with a grossly abnormal ileum and an additional 16 (4%) with abnormal histology in the ileum. Thus, >10% of patients with a normal

Table 3. Comparisons of colonoscopy yield by isolated colonoscopy compared with panendoscopy

	All (<i>n</i> = 374)	Colonoscopy only (<i>n</i> = 56)	EGD-colonoscopy (<i>n</i> = 318)	<i>p</i> value
Normal visual appearance of colon, <i>n</i> (%)				<0.001
Yes	249 (66.6)	22 (39.2)	227 (71.4)	
No	125 (33.4)	34 (60.7)	91 (28.6)	
Normal visual appearance of ileum, <i>n</i> (%)				<0.001
Yes	295 (78.9)	37 (66.1)	258 (81.1)	
Not reached	36 (9.6)	14 (25.0)	22 (6.9)	
No	43 (11.5)	5 (8.9)	38 (11.9)	
Normal visual appearance of colon and ileum, <i>n</i> (%)				<0.001
Yes	228 (60.9)	18 (32.1)	210 (66.0)	
No	110 (29.4)	24 (42.9)	86 (27.0)	
Ileum not reached	36 (9.6)	14 (25.0)	22 (6.9)	
Normal colon and ileum pathology, <i>n</i> (%)				0.001
Yes	196 (52.4)	18 (32.1)	178 (56.0)	
No	178 (47.6)	38 (67.9)	140 (44.0)	
Diagnostic yield colon and ileum, <i>n</i> (%)				<0.001
Normal	196 (52.4)	17 (30.3)	179 (56.3)	
IHA	32 (8.6)	4 (7.1)	28 (8.8)	
EA	146 (39.0)	35 (62.5)	111 (34.9)	
Normal visual EGD, <i>n</i> (%)				–
Yes	186 (59)	–	186 (59)	
No	129 (41)	–	129 (41)	
Normal EGD pathology, <i>n</i> (%)				–
Yes	106 (33.5)	–	106 (33.5)	
No	210 (66.5)	–	210 (66.5)	
Diagnostic yield EGD, <i>n</i> (%)				–
Normal	91 (28.9)	–	91 (28.9)	
IHA	95 (30.2)	–	95 (30.2)	
EA	129 (41)	–	129 (41)	

p value: chi-square tests (or Fisher's exact if counts <5) between C and EGD patient groups.

EA, endoscopically abnormal; IHA, isolated histologically abnormal; EGD, esophagogastroduodenoscopy.

endoscopic and histologic evaluation of the colon had abnormalities in the terminal ileum.

While the discrepancy between the gross appearance and histology is well-recognized with EGD [19–21], most reports from pediatric colonoscopy show good correlation between gross findings and histology [8–10]. In one study of 390 colonoscopies, there were 20 patients with abnormal histology with normal visual findings [8]; 8 of the 20 had a known diagnosis of IBD, 4 had symptoms highly suspicious for IBD, and another 3 patients were immunosuppressed due to either bone marrow transplant or nephrotic syndrome. Thus, only 5 patients had the perplexing problem of isolated histologic abnormalities. In the absence of other gross abnormalities, mild ileitis on biopsy presents a situation which requires close follow-up and possibly further investigation to determine whether this has any clinical significance, particularly in

patients without previous underlying disease. In our study, only 1 of 10 patients with IHA of ileum was subsequently determined to have new-onset IBD.

Our study showed that 46 patients (12%) had isolated abdominal pain as the indication for colonoscopy. The lower diagnostic yield of 24% (15% EA, 9% IHA) in this subgroup is in agreement with prior studies [7, 8, 10, 11, 16]. However, an important limitation in this finding is the difficulty in identifying some less frequent coexisting indications in a retrospective review, including first degree relatives with IBD, need for fecal microbiota transplantation, and abnormal studies from outside institutions. A recent large retrospective review with 652 colonoscopies showed a 0% yield when the indication was isolated abdominal pain [16].

In contrast to isolated abdominal pain, our study shows that an abnormal fecal calprotectin was associat-

Fig. 4. Ileum cannulation rate by doctor. The ileal intubation rate varied considerably among the 16 individual physicians.

ed with a high diagnostic yield of 83%. This finding is in agreement with many others showing the value of this test [16, 22–24]. In a study by Holtman et al. [22], the addition of fecal calprotectin to their models was the most useful test in determining the likelihood of IBD prior to endoscopy. In addition, calprotectin can be elevated in other colonic disorders including polyposis [25]. With the increasing use of biomarkers like calprotectin, it is anticipated that higher rates of diagnostic yield are likely. By monitoring diagnostic yields, individual providers may be able to alter their practice to more carefully select patients who will benefit from ileocolonoscopy.

This study showed that our center had a low serious complication rate; only 1 patient had an identified complication. In this patient, bleeding after polypectomy resulted in hospitalization, blood transfusion, and a repeat colonoscopy to control bleeding. Our low complication rate needs to be interpreted with caution in this retrospective study as some patients could have presented to outside emergency rooms or hospitals. Our complication rate is much lower than a recent report [26]. Kramer and Narkewicz [26] studied the frequency of adverse events that occurred within 72 h in a prospective observational pediatric cohort of 9,577 patients from a single center

who underwent either (or both) upper and lower endoscopy. The overall adverse event rate was 2.6% with 1.7% of all cases requiring unanticipated medical care. For diagnostic colonoscopy, the study identified a 2.3% rate of adverse events which resulted in referral to the emergency department or an unanticipated evaluation by a physician; this severity of adverse event occurred in 9.4% of patients following polypectomy and included 4 of 128 who had a perforation.

Our study focused primarily on colonoscopy rather than EGD on diagnostic yield among clinicians primarily because EGD diagnostic yield is more difficult to interpret due to the high frequency of minor pathologic findings [20, 21]. In our study, <30% of esophagogastroduodenoscopies were considered normal both endoscopically and based on histology; this is in agreement with previous pediatric studies. In a systematic review of 1,871 children from 18 articles, Thakkar et al. [20] found that nonspecific histologic gastrointestinal inflammatory lesions varied between 23 and 93%. Similarly, microscopic non-eosinophilic esophagitis has been noted in 20% of children and is more likely to indicate functional heartburn than nonerosive reflux disease [21].

The findings of this study have several limitations. First of all, this study included only patients who were

healthy enough to have a colonoscopy in an ambulatory center. It is likely that the diagnostic yield would have been higher if hospitalized patients were included in this study. Second, with retrospective reviews, the quality of the data relies on adequate documentation. Some of the patients included may have had symptoms or laboratory studies that were not recorded. The definitions of charted clinical variables and endoscopy findings are not standardized. Even for terms like “diarrhea” each clinician may have a different definition. Additional limitations are related to the subjective nature of visual interpretation of endoscopic findings as well as the frequency and variability in the use of endoscopic biopsies. In addition, as is common in clinical practice, the histology was reviewed by only one pathologist for each patient; this could have led to both overinterpretation or underinterpretation of the findings. Finally, other parameters including bowel preparation and complications are more readily detected in prospective studies with standardized metrics. While a retrospective study has its limitations, one advantage is that the study would not have influenced individual clinicians in making decisions.

Conclusions

This study highlights the provider variability in diagnostic yield in an ambulatory pediatric gastroenterology private practice along with the variability in quality metrics like ileal intubation. In addition, this study confirms the value of calprotectin as predictor for higher diagnostic

yield. This single-center retrospective study found diagnostic yields in excess of 40% and ileal intubation rates of >90%.

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Statement of Ethics

IRB approval was obtained for our retrospective chart review.

Disclosure Statement

The authors have no conflicts of interest to declare.

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Author Contributions

J.A.H.: participated with study design/concept, analysis/interpretation, drafting/revision of manuscript. J.F.: analyzed the data, ran the statistical programs, and developed the figures and tables. She helped write the statistical information in the manuscript. E.D.: participated with data acquisition and with analysis of data. J.D.L.: participated with study design/concept, helped analyze data, and provided critical review of draft/revision for important intellectual content.

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