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NATIONAL TRENDS IN ELECTIVE ILEAL POUCH-ANAL ANASTOMOSIS
FOR ULCERATIVE COLITIS

A Master's Thesis Presented

By

Chau Maggie Hoang, MD

Submitted to the Faculty of the
University of Massachusetts Graduate School of Biomedical Sciences, Worcester
in partial fulfillment of the requirements for the degree of

MASTER OF SCIENCE

June 5, 2018

BIOMEDICAL SCIENCES
HEALTH SERVICES RESEARCH

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the student has met all master's degree graduation requirements of the school.

Mary Ellen Lane, PhD
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Abstract

Background: Recent national trends and distribution of ileal pouch-anal anastomosis (IPAA) procedures for patients with ulcerative colitis (UC) are unknown. We examined the frequency of use of elective IPAA procedures among patients with UC and the distribution of IPAA procedures across more than 140 U.S. academic medical centers and their affiliates.

Methods: Data were obtained from the University HealthSystem Consortium for patients with a primary diagnosis of UC admitted electively between 2012 and 2015.

Results: The mean age of the study population (n=6,875) was 43 years and 57% were men. Among these, one-third (n=2,307) underwent an IPAA, while two-thirds (n=4,568) underwent colectomy, proctectomy, proctocolectomy or other procedures. The proportion of IPAA cases among all elective admissions was relatively stable at 33-35% during the years under study. A total of 131 hospitals, out of 279 hospitals participating in the UHC, performed IPAA. The median number of IPAA cases performed annually was 1.9 [IQR 0.8 – 4.3]. Nearly one half (48%) of these cases were performed by the top ten hospitals. Overall, only a total of 30 centers performed \geq five elective IPAA cases annually.

Conclusions: Although the frequency of elective IPAA surgery in recent years has been stable, nearly one half of all IPAA cases was performed at ten hospitals. The concentration of IPAA cases at high-volume centers, and the steady number of cases

performed annually, have potential implications for fellowship training, patient clinical outcomes and access to care.

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Preface

Accomplished work not presented as part of this thesis:

Hoang CM, Alavi K, Flahive JM, Sturrock PR, Maykel JA, Davids JS. "Impact of the 'Weekend Effect' for Hospital Discharges on Readmissions After Elective Colectomy. Accepted for publication in *Diseases of the Colon and Rectum*.

CHAPTER I: Introduction

The management of patients with ulcerative colitis (UC) has evolved in recent decades. Currently, the treatment of choice is medical management, which includes the use of 5-aminosalicylic acid, corticosteroids, immunomodulators, tumor necrosis factor (TNF)- α antagonists, and anti-integrin antibodies.¹ Surgery is generally reserved for those who are refractory to medical treatment, develop complications or experience severe side-effects.¹ Total proctocolectomy with end ileostomy, or restorative proctocolectomy with ileal pouch-anal anastomosis (IPAA), done in one, two, or three stages, are the mainstays of elective surgical management for UC.² While there appears to be a trend toward better long-term outcomes for those with early disease after the introduction of biologics,³ there is no clear evidence that the rate of IPAA has decreased over time.

A prior observational study evaluated trends in the 3-stage versus 2-stage approach for IPAA using data from the American College of Surgeons National Surgical Quality Improvement Program (ACS NSQIP).⁴ The investigators concluded that trends in the proportion of 3-stage vs 2-stage pouch procedures have remained relatively stable between 2007 and 2011. However, due to the sampling cycle of NSQIP, the overall number of IPAA procedures performed nationwide, and annual trends therein, could not be accurately determined. The minimum number of IPAA procedures for graduating colorectal surgical fellows is presently five and not all fellows regularly meet this requirement.⁵ This has led to a growing concern that either there is a decreasing trend

in the number of pouch procedures performed annually, potentially due to improvements in modifying the natural history of the disease, or that there is a redistribution of these surgical procedures to high-volume centers.

We examined trends in the volume and distribution of elective IPAA procedures on patients with UC from 2012 to 2015 using information from the University HealthSystem Consortium (UHC) national database. Our primary study objective was to determine the frequency of IPAA pouch surgery cases performed in recent years among patients admitted electively with a primary diagnosis of UC. Our secondary aim was to describe the distribution of IPAA cases at the 140 participating academic centers and their affiliates in this large database. We hypothesized that there was either a decrease in the frequency of IPAA procedures performed among those admitted electively with a primary diagnosis of UC or that a large proportion of IPAA cases was being done at a small proportion of hospitals participating in the UHC.

CHAPTER II: Methods

Data Source

Data were obtained from the UHC, a national clinical database, on all adult patients admitted electively between January 2012 through August 2015 with a primary diagnosis of UC (ICD-9 556.X). A detailed description of this database has been previously reported.⁶ Data from the fourth quarter of 2015 and beyond were not included because a change in vendor during that interval affected the inclusion of all inpatient records into the database, and resulted in significant missing data for that quarter. Patient's demographic data included their age, sex, race, and insurance carrier. Clinical data included hospital length of stay, intensive care unit stay and admission 3M APR-DRG Severity of Illness Score; this score, which is calculated upon admission based on existing comorbidities, is categorized as either minor, moderate, major, or extreme. Receipt of an IPAA procedure was identified using ICD-9 code 459.5, for adults admitted electively. Among those who were admitted electively but did not undergo an IPAA, ICD-9 codes were used to identify performance of total abdominal colectomy or TAC (ICD-9 458.1-458.3), partial colectomy (ICD-9 173.1-173.9, 457.1-457.9), proctectomy (486.3-486.9, 485.0-485.2, 485.9), or total proctocolectomy with end ileostomy (TAC with proctectomy and ICD-9 462.3). Among hospitals performing IPAA, we also identified the volume of low anterior resections (LAR; ICD-9 486.3) performed for rectal cancer (ICD-9

154.0-154.1, 154.8) in order to more clearly describe the practice patterns, specifically pertaining to complex pelvic dissections, observed among the included hospitals. In the UHC, all hospitals have unique de-identified hospital codes that cannot be linked back to individual hospitals, but the names of hospitals that contribute information to the database are known. The Institutional Review Board at the University of Massachusetts Medical School granted exemption status for this observational study.

Outcome Measures

The primary study outcome was the frequency of IPAA procedures performed among all elective admissions for UC at participating study sites during the period under study (2012-2015). Our secondary study endpoint was the distribution of elective IPAA cases across academic medical centers and their affiliates among patients with a primary admission diagnosis of UC.

Data Analysis

Univariate analysis was performed to compare differences in various clinical characteristics between patients with UC who did and did not undergo IPAA and the clinical characteristics and outcomes among the IPAA group across the different study years. Student's t-test and analysis of variance were used for comparisons of continuous

data, and chi-square test was used for comparisons of categorical variables.

Comparisons were considered statistically significant at an alpha level of 0.05. Hospitals in the study were sorted according to de-identified codes to determine the total and mean number of IPAA cases performed annually in patients with UC at each unique hospital. Imputed data for the fourth quarter of 2015 were used to verify no significant change in the calculated average number of procedures performed per hospital due to missing fourth quarter data. We imputed the total number of cases per hospital for 2015 by dividing the reported number of cases for the first three quarters by 0.75. All statistical analyses were done using STATA version 14.2 (StataCorp. 2015. *Stata Statistical Software: Release 14*. College Station, TX: StataCorp LP).

CHAPTER III: Results

Study Population Characteristics

Between 2012 and 2015, a total of 6,875 patients were admitted electively with a primary diagnosis of UC. The mean age of this patient population was 43 years, 57% were men, 85% were white, and 73% had private insurance (Table 1). One-third (n=2,307) underwent an IPAA during the years under study. Among the non-IPAA group (n=4,568), the majority underwent either total abdominal colectomy (36%), proctectomy (25%), partial colectomy (7%) or total proctocolectomy with end ileostomy (2%). Among those who underwent an IPAA, a higher proportion had private insurance and a smaller proportion had severe or extreme severity of illness score on admission compared with patients who did not undergo an IPAA (p=0.001).

Trends in Elective IPAA Utilizations

The frequency of IPAA among all elective admissions with a primary diagnosis of UC in adults was stable at 33-35% from 2012 to 2015 (Fig. 1). During the years under study, there was no significant change in patient's average age, median length of hospital stay, severity of illness score, or in the proportion of patients requiring admission to the ICU among those who underwent an IPAA.

Distribution of Elective IPAA Cases

Among the 279 hospitals in the UHC database, there were 131 hospitals that performed IPAA (Fig. 2). The median number of cases performed on an annual basis at these hospitals was 1.9 [IQR 0.8 – 4.3]. Nearly one half (48%) of the cases were performed by only ten hospitals (performing an average of 30 pouches procedures annually; range between 12 to 96 pouches annually). Overall, only a total of 30 centers (out of 131 centers that performed IPAA) performed ≥ 5 elective IPAA cases per year.

We reported results over the period from January 2012 to August 2015. To evaluate the effect of the missing fourth quarter data from 2015 on the calculated mean number of cases per center, we compared the results to a second dataset that included imputed data from the fourth quarter of 2015. Comparing our original findings with imputed data yielded no change in the number of centers performing ≥ 5 elective IPAA cases per year.

Distribution of LAR for Rectal Cancer

Among the hospitals that performed IPAA procedures, we evaluated the distribution of low anterior resection (LAR) performed for rectal cancer at those centers. This additional step was performed to assess whether the skewed distribution was unique to IPAA cases alone or whether a similar distribution would be observed in other types of complex pelvic dissections and reconstruction procedure in colorectal surgery at these hospitals.

The median number of LAR cases performed per center on an annual basis was 4 [IQR 1.25-13.5]. The centers that performed higher annual volume (ten or more) of IPAA cases had a varied distribution in the annual number of LAR cases (Fig. 3). These centers performed from 6 LAR procedures to over 60 LAR procedures per year. Centers that performed a lower volume of IPAA (fewer than ten) cases annually also had a varied distribution in the annual number of LAR procedures, with some centers performing over 60 LAR procedures annually for rectal cancer (Fig. 3). The top ten centers that performed 48% of IPAA cases from 2012-2015 performed only 18% of total LAR cases.

CHAPTER IV: Discussion

The results of this study suggest that the frequency of IPAA surgery among elective admissions for UC remained stable during the years under study. Among the 279 hospitals in the UHC, ten hospitals performed nearly one half of the elective IPAA cases nationally. Furthermore, our study suggests that many centers that perform a large number of complex pelvic dissections for rectal cancer are low-volume pouch centers. The disproportionate distribution of these case volumes has potential implications for patients' clinical outcomes and overall access to care.

It has been shown previously that the risk of pouch failure, defined as requiring excision or requiring permanent ileostomy,⁷ is more than two-fold higher at very low volume centers that perform 1-5 cases annually compared with high-volume centers that perform more than 20 cases annually.⁸ This observational study of 1991 patients from Denmark who underwent an IPAA from 1980-2013, with a median follow-up of 11 years, determined the pouch failure rate of 9% at 5 years, 12% at 10 years and 18% at 20 years.⁸ In another study of 4,525 patients who underwent an IPAA procedure between 1983 and 2015 at a single high-volume center in the US, with a median follow-up of 10 years, the investigators observed a pouch failure rate of 4.8%.⁹

While only a small percentage of centers performed a large proportion of all pouch procedures during the years under study in the present study, this pattern was not observed for other complex pelvic dissections. Whereas the majority of centers

included performed only a handful of IPAA procedures, many of these centers performed a significant number of total mesorectal excisions for rectal cancer. These data suggest that, despite a lower volume of pouch surgery, surgeons at these lower volume centers have the technical experience required to perform complex pelvic dissections. The reasons why many patients with UC are diverted away to certain centers for IPAA remain unclear. However, the direct association between these findings and complex pelvic procedure volume-outcome relationship as it relates to restorative proctocolectomy warrants further investigation.

This study identified a disproportionate distribution of case volume which may have implications for surgical training. Only 60% of colon and rectal fellowship training programs participate in the UHC database. Inasmuch, we cannot directly use UHC data to determine whether all surgical training programs are providing sufficient numbers of cases for their fellows; however, we can report on cases by graduating fellows and fellowship training programs. In 2013 and 2014, more than 35% of colon and rectal fellows did not meet the graduation requirement for the number of IPAA cases.⁵ In 2015, 10% of colon and rectal training programs did not meet the IPAA case requirement; 12% (11/94) of fellows did not meet pouch procedure requirements of five cases per year, despite an overall reported national average of 8.4 cases per fellow for that year.⁵ In our study, the median number of IPAA procedures performed per year was 1.9 [IQR 0.8-4.3]. This discrepancy can be explained by the fact that almost half of the IPAA cases reported in the UHC database are performed by only ten academic

centers. Despite the recent reduction in IPAA case requirement from 8 to 5 cases for fellowship training, meeting these requirement for graduation remains a focal point of concern for training programs and the American Board of Colon and Rectal Surgery.

Study Strengths and Limitations

A particular strength of this study is that UHC is a national database that contains all inpatient data on 90% of academic hospitals and their affiliates, allowing us to evaluate national trends and distribution of IPAA cases in patients with UC. This study is the first to evaluate the national distribution of IPAA procedures among patients with UC.

Another strength of this study was an examination of the distribution of other complex pelvic dissections, in addition to IPAA, to determine any changes in the distribution of other complex pelvic dissections at participating study centers. This observational study, however, is not without limitations. Hospital codes in UHC are also de-identified; therefore, we were unable to identify specific high or low performing hospitals or their characteristics. Furthermore, zip code data were also not available, precluding an assessment of possible geographic differences in low-volume versus high-volume centers or referral patterns. We also did not study the short- and long-term clinical outcomes of these patients, as they were not the focus of this study, but future work comparing outcomes at higher- and lower-volume centers will offer a better understanding of quality of care for these patients.

CHAPTER V: Conclusions

Although the frequency of elective IPAA surgery for patients with UC was stable between 2012 and 2015, nearly one-half of all IPAA cases was performed at only ten hospitals in the U.S. The large concentration of cases at select hospitals and the steady number of cases performed annually has potential implications not only for case requirements but also for the adequate provision of training in IPAA during colorectal fellowship across the country. Potential changes include decreasing the minimum number of IPAA case requirements for fellows in training or allowances for fellows to travel to high-volume performing centers for pouch cases. Further work should evaluate whether the concentration of IPAA cases at high-volume centers has implications for potential differences in patients' clinical outcomes and access to care.

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Tables

Table 1. Characteristics of Patients with Ulcerative Colitis According to Ileal Pouch-Anal Anastomosis (IPAA) Status

Characteristics	IPAA (n=2,307)	Non-IPAA (n=4,568)	p-value
Age, mean, years (+/-SD)	40 (+/-14)	45 (+/-17)	<0.001
Male sex	56.7%	56.5%	0.87
White race	86.3%	84.0%	0.01
Insurance type^a			0.001
Private	81.0%	69.2%	
Medicare	6.3%	17.6%	
Medicaid	7.8%	6.9%	
Admission Severity of Illness			0.001
Minor	10.6%	11.2%	
Moderate	85.0%	76.9%	
Severe/Extreme	4.4%	11.9%	
Length of Stay, median days (IQR)	5 (4-7)	5 (4-8)	

^a“Other” not shown

Figures

Figure 1. Trends in Frequency of Ileal Pouch-Anal Anastomosis Cases Among All Elective Admissions for Ulcerative Colitis

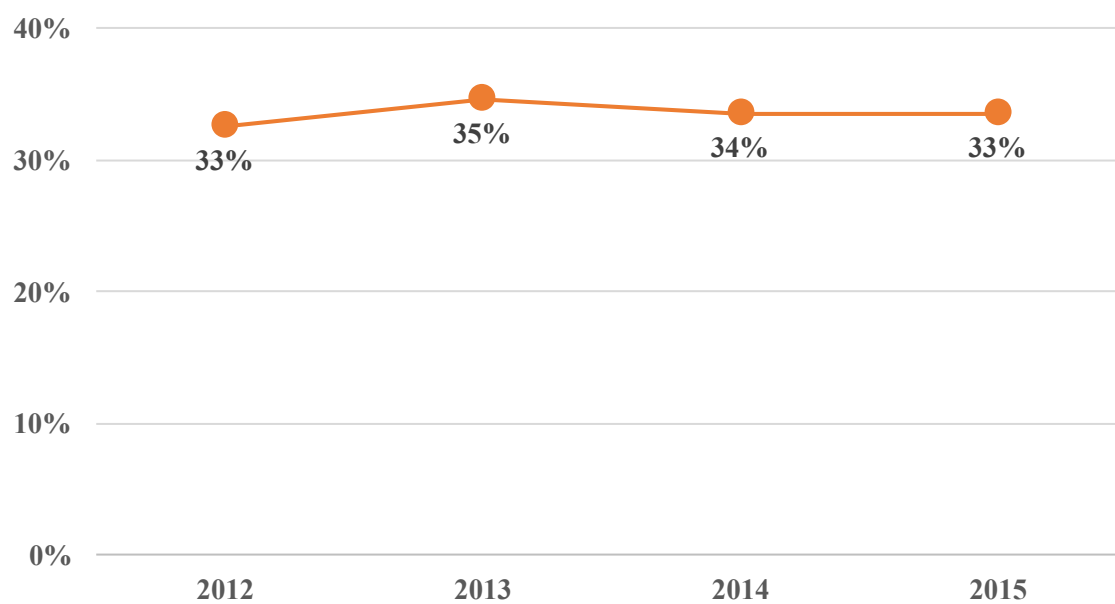


Figure 2. Distribution of Ileal Pouch-Anal Anastomosis (IPAA) Cases From 2012-2015 by: A) Hospital Volume and B) Case Volume

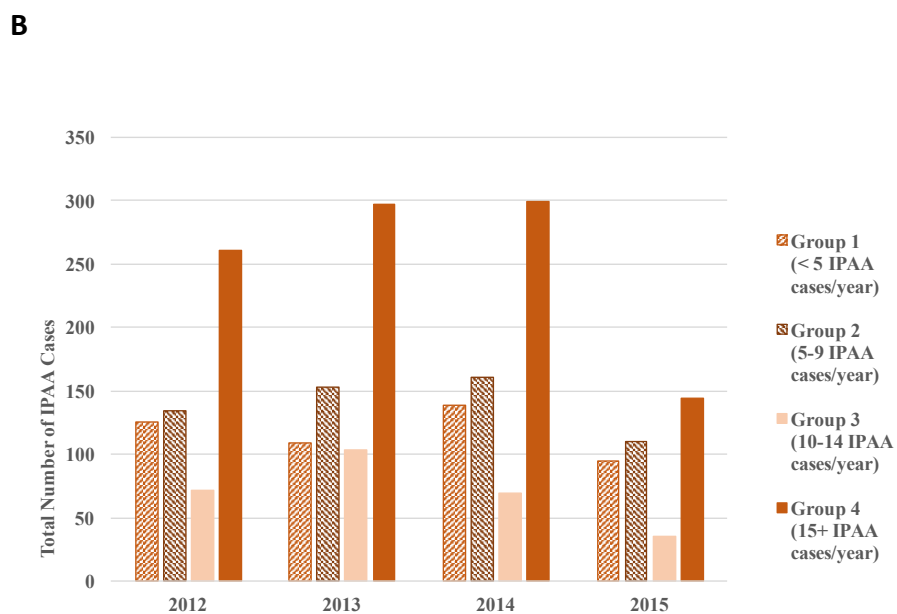
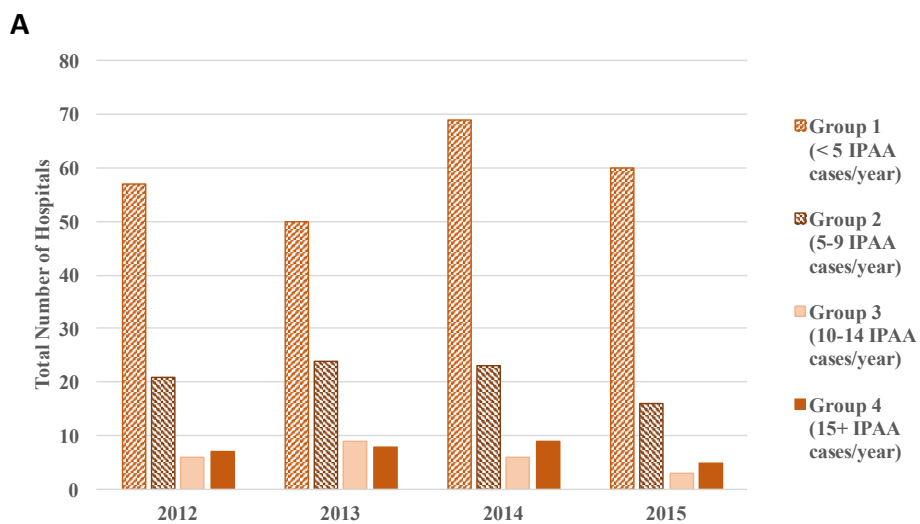


Figure 3. Distribution of Low Anterior Resection (LAR) Cases for Rectal Cancer Among Hospitals That Performed Ileal Pouch-Anal Anastomosis (IPAA) Between 2012 and 2015

