FINAL ID: S15

TITLE: Fragility of Statistically Significant Outcomes in Colonic Diverticular Disease Randomized Trials

ABSTRACT BODY:

Purpose/Background: The Fragility Index (FI) can assess the robustness of statistically significant p-values derived from RCTs. It is a representation the minimum number of study participants who would need to be converted from a non-responder to a responder, in order to increase the p-value above 0.05. This concept was recently applied to RCTs published in the field of colorectal surgery. However, RCTs evaluating both benign and malignant diseases were included and the time frame during which RCTs were evaluated was relatively short. As such, we have designed a study aimed at assessing the FI of RCTs assessing the efficacy of interventions for patients with colonic diverticular disease since 2010.

Methods/Interventions: MEDLINE, Embase, and CENTRAL were searched from 2010 to June 2022. RCTs with parallel design comparing two interventions for patients with colonic diverticular disease reporting a statistically significant dichotomous primary outcome were included. Walsh et al.'s described method of calculating FI was utilized for all statistically significant dichotomous outcomes. Univariable linear regression was performed to determine the association between FI and sample size, number of outcome events, journal impact factor, funding, p-value, and loss to follow-up.

Results/Outcomes: Following review of 914 relevant citations, 15 RCTs published between 2010 and 2022 met inclusion criteria. Nine of the RCTs evaluated surgical interventions (60.0%) and six evaluated medical interventions (40.0%). Eight RCTs evaluated patients with complicated diverticular disease (53.3%), six evaluated patients with uncomplicated disease (40.0%), and one evaluated patients with diverticular bleeding (6.7%). Three RCTs were industry funded (23.1%). The mean number of patients randomized per RCT was 92 (SD 35.3). The mean number of patients lost to follow-up per RCT was 9 (SD 11.4). The mean number of combined events between arms for the primary outcome per trail was 37 (SD 30.8) and the mean p-value across all included RCTs was 0.017 (SD 0.02). The median FI was 0 (range: 0-2), meaning that upon creation of a 2x2 table and computation of a two-sided Fisher exact test, the majority of included RCTs did not demonstrate significant findings. There were no significant associations between FI and sample size, number of outcome events, journal impact factor, funding, p-value, or loss to follow-up.

Conclusions/Discussion: Recent RCTs evaluating both medical and surgical interventions for colonic diverticular disease with significantly different dichotomous primary outcomes are not robust. The majority of these RCTs no longer demonstrate significant findings upon removal of the statistical adjustments from the original publication. Future RCTs evaluating patients with colonic diverticular disease require larger sample size and consideration of FI when determining sample size.

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AUTHORS (FIRST NAME, LAST NAME): T. McKechnie[1], S. Yang[2], K. Wu[2], S. Sharma[1], Y. Lee[1], L. Park[1], A. Doumouras[1], D. Hong[1], C. Eskicioglu[1]

AUTHORS/INSTITUTIONS: T. McKechnie, S. Sharma, Y. Lee, L. Park, A. Doumouras, D. Hong, C. Eskicioglu, McMaster University Department of Surgery, Hamilton, Ontario, CANADA|S. Yang, K. Wu, McMaster University Michael G DeGroote School of Medicine, Hamilton, Ontario, CANADA|

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FINAL ID: S16

TITLE: Can Non-operative Management of Acute Complicated Diverticulitis be Successfully Treated With a Future Hospital-at-Home Program? A Retrospective Cohort Study

ABSTRACT BODY:

Purpose/Background: Hospital at Home (HaH) programs generated high interest during the COVID-19 pandemic. A HaH program offering virtual monitoring and timely access to out-patient diagnostic and interventional procedures was developed at our institution for patients with cardiopulmonary pathologies. As of yet, no HaH program has included patients with acute complicated diverticulitis (ACD). Since the majority of ACD admissions are successfully managed nonoperatively, we sought to retrospectively evaluate the proportion of eligible ACD admissions that required care that could be offered by a future HaH program.

Methods/Interventions: This IRB-approved retrospective cohort study included adult patients admitted for ACD (Hinchey stage Ib-IV) at our institution from 01/2018-03/2022 who would meet criteria for our future HaH program ("HaH eligible ACD admissions") on presentation to the emergency room including: hemodynamic stability, tolerating oral intake, and adequate analgesia. Admissions with peritonitis or needing urgent surgery at presentation were excluded. The primary outcome was the proportion of HaH eligible ACD admissions that only required care available within a future HaH program. Secondary outcomes were total hospital bed-days including: idle-bed days defined as days spent in hospital with no diagnostic/interventional procedures, HaH-bed days as days where out-patient procedures available within HaH occured, and inpatient bed-days as days where patients had to physically be in hospital (surgery, total parenteral nutrition).

Results/Outcomes: Of 242 admissions for ACD during the study period, 59 (24.4%) had ACD with peritonitis, hemodynamic instability and/or urgent surgery on presentation and were excluded. Thus, the study cohort included 183 (75.6%) HaH eligible ACD admissions: 53.6% male, mean age 59.7±14.7years, mean body mass index 28.2±4.9kg/m^2, and mean Charlson Comorbidity Index 2.2±2.2. In this cohort, imaging showed 49.2% had abscesses (82%pericolic, 18%distant) and 47.0% extraluminal gas (79.3%pericolic, 20.7%distant). Percutaneous drainage was needed in 12.6%. Overall, 177 (96.7%) admissions only required care available with HaH, while 2 (1.1%) required TPN and 6 (3.3%) had same-admission surgery. Median total hospital bed-days was 4 [IQR3-7].Median idle, HaH and in-patient bed-days were 4 [IQR3-5], 0 [IQR0-1.5] and 0 [IQR0-0]. Of 1,066 total hospital bed-days for HaH eligible ACD admissions: 827, 185 and 54 were idle, HaH and in-patient bed-days, respectively. A HaH program for non-operative management of ACD could have saved 1,012 hospital bed-days during the study period.

Conclusions/Discussion: Most admissions for non-operative management of ACD can be treated in novel HaH programs. In light of our findings, we intend to perform a prospective feasibility trial of HaH for non-operative management of ACD.

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TABLE 1. CHARACTERISTICS OF ADMISSIONS FOR ACUTE COMPLICATED DIVERTICULITIS (N=183)

Variable	Mean ± SD; Median [Q1-Q3]; N (%)
Hinchey (%)	
0	2 (1.1%)
IA	90 (49.2%)
IB	74 (40.4%)
II	17 (9.3%)
Abscess on CT	90 (49.2%)
< 5cm	68 (75.6%)
≥ 5 cm	22 (24.4%)
Pericolic	74 (82%)
Pelvic/Distant	16 (18%)
Extraluminal gas	86 (47.0%)
Pericolic	68 (79.3%)
Distant	18 (20.7%)
Operative management	6 (3.3%)
Percutaneous drainage	23 (12.6%)
Duration antibiotics, days	20.7 ± 17.6 16 [13 - 20]
Duration IV	9.0 ± 15.3 4 [2 - 7]
Duration PO	13.4 ± 12.5 11 [10 - 14]

TABLE 1. CHARACTERISTICS OF ADMISSIONS FOR ACUTE COMPLICATED DIVERTICULITIS (N=183)

IMAGE CAPTION: TABLE 1. CHARACTERISTICS OF ADMISSIONS FOR ACUTE COMPLICATED DIVERTICULITIS (N=183)

AUTHORS (FIRST NAME, LAST NAME): N. Boukhili[1], N. G. Caminsky[1], S. Faris-Sabboobeh[2], M. Demian[2], M. Boutros[2]

AUTHORS/INSTITUTIONS: N. Boukhili, N.G. Caminsky, McGill University, Montreal, Quebec, CANADA|S. Faris-Sabboobeh, M. Demian, M. Boutros, Sir Mortimer B Davis Jewish General Hospital, Montreal, Quebec, CANADA|

FINAL ID: S17

TITLE: Transplant and Immunosuppressed Patients Undergoing Diverticular Resections: High Risk for Peri-operative Morbidity and Mortality?

ABSTRACT BODY:

Purpose/Background: Transplant (TXP) and immunosuppressed (IS) patients are a unique subgroup of patients who have been reported to have a high morbidity and mortality rate after resection for diverticular disease. The aim of this study was to compare outcomes among this patient group with a propensity-score matched cohort of similar patients. We hypothesized that TXP and IS patients have similar morbidity and mortality rates compared to matched controls.

Methods/Interventions: Our prospectively maintained database was queried for TXP and IS patients undergoing operative intervention for diverticular disease from 2010-2017. The propensity matched cohort included patients without underlying immunosuppression and patients were matched based on age, gender, ASA class, and elective or emergent surgery. Charts were retrospectively reviewed for data accuracy. Propensity matching and risk adjusted calculations were performed using R.

Results/Outcomes: Fifty-three TXP/IS patients were identified during the study period. Of these, 31 (58.5%) had undergone TXP and 22 (41.5%) were IS patients. 53 propensity matched controls were obtained. Within the overall dataset, age was 63.4 years (median, IQR 53-78), with 48 (45.3%) females. Seventy-three (68.9%) were ASA category 3 and 33 (31.1%) were ASA category 4. There were no significant differences between the TXP/IS and matched groups in terms of baseline characteristics, operative indications, open approach including conversions (69.8% overall), minimally invasive (30.2% overall) and emergent surgery (55.7% overall). There was a longer operative time in the TXP/IS group (209 vs 147.5 minutes, p=0.03). In addition, the TXP/IS group had a higher stoma rate (86% vs 53%, p<0.001), and a lower rate of primary anastomosis (11% vs. 39%, p<0.001) (Table 1). There was no significant difference in rate of grade 3 or greater Clavien-Dindo complications (28.3% vs. 37.7%, p=NS), mortality (13.2% vs 13.2%, p=NS), or preoperative Hinchey classification. The TXP/IS group had a significantly longer length of stay (11 vs 8 days, (p=0.01).

Conclusions/Discussion: This propensity matched analysis has not identified a higher rate of morbidity or mortality in TXP/IS patients undergoing diverticular resection compared with propensity matched controls. TXP/IS patients were observed to have a significantly higher stoma rate. The use of stoma in TXP/IS patients should be considered when clinically indicated.

(no table selected)

Table 1.

	TKP/S (n=53)	Propensity matched controls (n=53)	p-value
Disease Type			
Uncomplicated	19 (35.8%)	17 (32.1%)	
Hinchey 1	13(24.5%)	6 (11.3%)	
Hinchey 2	6 (11.3%)	6 (11.3%)	
Hinchey 3	8 (15.1%)	11 (20.8%)	0.10
Hinchey 4	4 (7.5%)	4 (7.5%)	
Fistula	1 (1.9%)	7 (13.2%)	
Stricture	1 (1.9%)	2 (3.8%)	
Bleeding	1 (1.9%)	0	
Stoma			
Hartmanns	25 (47.2%)	19 (35.9%)	
DLI	21 (39.6%)	9 (17%)	*0.001
Primary Anastomosis	6 (11.3%)	21 (39.6%)	
Other[a]	1 (1.9%)	4 (7.5%)	
Clavien-Dindo Complications			
No complication	20 (40%)	18 (34%)	
Grade 1	6 (12%)	8 (15.1%)	
Grade 2	9 (18%)	7 (13.2%)	0.76
Grade 3	1 (2%)	4 (7.5%)	
Grade 4	8 (15.1%)	8 (15.1%)	
Grade 5	7 (13.2%)	7 (13.2%)	

[a]Other; Total abdominal colectomy & end ileostomy, laparoscopic lavage, DLI, intra-op cardiac arrest

IMAGE CAPTION:

AUTHORS (FIRST NAME, LAST NAME): N. Foley[1], M. Maspero[1], T. M. Connelly[1], E. P. Lincango[1], L. F. Sobrado[1], J. Wong[1], L. C. Duraes[1], M. Valente[1], A. E. Kanters[1], S. D. Holubar[1], H. Kessler[1]

AUTHORS/INSTITUTIONS: N. Foley, M. Maspero, T.M. Connelly, E.P. Lincango, L.F. Sobrado, J. Wong, L.C. Duraes, M. Valente, A.E. Kanters, S.D. Holubar, H. Kessler, Dr, Cleveland Clinic, Cleveland, Ohio, UNITED STATES|