Home-based management of acute complicated diverticulitis

Neyla Boukhili, MD

260687916

Department of Surgical and Interventional Sciences

McGill University, Montreal

March 2024

A thesis submitted to McGill University in partial fulfillment of the requirements of the degree of Master's of Science in Surgical and Interventional Sciences

TABLE OF CONTENTS

ABSTRACT

Introduction: Despite evidence favoring outpatient management for acute uncomplicated diverticulitis, hospitalizations for acute complicated diverticulitis (ACD) are on the rise. Hospital-at-Home (HaH) programs generated interest during the COVID-19 pandemic, leading to the development of such a program offering virtual monitoring at our institution for patients with cardiopulmonary pathologies. A similar program for management of acute complicated diverticulitis (ACD) does not yet exist. Objectives: Evaluate the proportion of ACD admissions that could potentially be managed with HaH and develop a protocol to determine the feasibility and the safety of a pilot HaH program for non-operative management of ACD.

Methods: A retrospective cohort study was conducted at an academic tertiary care center from 01/2018 – 03/2022. This was followed by patient and surgeon surveys conducted from 02/2023-08/2023. Hemodynamically stable adult patients admitted with acute complicated diverticulitis were included. The primary outcome was the proportion of admissions dedicated to clinical observation and drug administration during which no intervention was performed. A protocol was then developed for a non-randomized feasibility study in accordance with CONSORT guidelines. Adult (≥18 years) patients with acute complicated diverticulitis admitted to HaH who do not require immediate surgery and are hemodynamically stable will be included. Participants will wear devices that measure vitals at home and will be contacted by a nurse and physician at least once a day. The HaH intervention will end once patients meet discharge criteria or if they require admission to the hospital. Primary outcome of the pilot study will be feasibility of the HaH program will be defined as 60% of participants *not* requiring unplanned healthcare visits within 30 days of admission to HaH. Secondary outcomes include readmissions at 60 days, number of saved in-hospital bed-days, cost, and patient satisfaction. When accounting for the

rate of eligible admissions per year and potential success, we estimate a 80% success in a recruited sample of 80 patients, resulting in a 95% confidence interval of 71.2% – 88.8%.

Results: Of 242 admissions, 59 (24.4%) were excluded for critical illness on presentation and the cohort included 183 (75.6%) admissions for non-operative management: 53.6% male with mean age 59.7 ± 14.7 years and Charlson Comorbidity Index 2.2 ± 2.2. Surgical intervention was needed for only 3.3% of patients, while 56.8% received clinical observation and intravenous medications alone. Of 1,066 total hospital bed-days generated: 827, 185 and 54 were idle, active, and strict inpatient bed-days, respectively. A survey found 65.1% of these patients (47%) were interested in home-based care, with safety concerns being the main reason for disinterest. An additional survey found colorectal surgeons at our institution had a positive perception of home-based management for complicated diverticulitis but had concerns regarding the impact on their workload.

Conclusions: Most admissions for non-operative management of acute complicated diverticulitis are dedicated to observation and have the potential to be treated in a HaH program. The outlined protocol describes the pilot HaH developed for this patient population.

RÉSUMÉ

Introduction : Malgré les preuves en faveur de la gestion ambulatoire de la diverticulite aiguë non compliquée, les hospitalisations pour diverticulite aiguë compliquée (DAC) sont en augmentation. Les programmes Hôpital-à-Domicile (HaD) ont suscité de l'intérêt pendant la pandémie de COVID-19, menant au développement d'un tel programme offrant une surveillance virtuelle dans notre établissement pour les patients atteints de pathologies cardiopulmonaires. Un programme similaire pour la gestion de la DAC n'existe pas encore. Objectifs : Évaluer la proportion des admissions pour DAC qui pourraient potentiellement être gérées par HaD et déterminer la faisabilité et la sécurité d'un programme pilote HaD pour la gestion non opératoire de la DAC.

Méthodes : Une étude de cohorte rétrospective a été menée dans un centre de soins tertiaires universitaires du 01/2018 au 03/2022. Cela a été suivi par des enquêtes auprès des patients et des chirurgiens menées du 02/2023 au 08/2023. Les patients adultes hémodynamiquement stables admis avec une diverticulite aiguë compliquée ont été inclus. Le critère de jugement principal était la proportion des admissions consacrées à l'observation clinique et à l'administration de médicaments au cours desquelles aucune intervention n'a été réalisée. Un protocole a ensuite été élaboré pour une étude de faisabilité non randomisée, conformément aux directives CONSORT. Les patients adultes (≥18 ans) atteints de DAC admis à HaD, qui ne nécessitent pas une chirurgie immédiate et sont hémodynamiquement stables, seront inclus. Les participants porteront des appareils mesurant les signes vitaux à domicile et seront contactés par une infirmière et un médecin au moins une fois par jour. L'intervention HaD se terminera une fois que les patients répondront aux critères de sortie ou s'ils nécessitent une admission à l'hôpital. Le critère de

jugement principal de l'étude pilote sera la faisabilité du programme HaD définie comme 60% des participants ne nécessitant pas de visites de soins de santé non planifiées dans les 30 jours suivant l'admission à HaD. Les critères de jugement secondaires comprennent les réadmissions à 60 jours, le nombre de jours-lits d'hôpital économisés, les coûts, et la satisfaction des patients. En tenant compte du taux d'admissions éligibles par an et du succès potentiel, nous estimons un succès de 80% dans un échantillon recruté de 80 patients, résultant en un intervalle de confiance de 95% de 71,2% à 88,8%.

Résultats : Sur 242 admissions, 59 (24,4%) ont été exclues pour maladie grave à la présentation et la cohorte comprenait 183 (75,6%) admissions pour gestion non opératoire : 53,6% d'hommes avec un âge moyen de 59,7 ± 14,7 ans et un indice de comorbidité de Charlson de 2,2 ± 2,2. Une intervention chirurgicale n'a été nécessaire que pour 3,3% des patients, tandis que 56,8% ont reçu uniquement une observation clinique et des médicaments intraveineux. Sur un total de 1 066 jours-lits d'hôpital générés : 827, 185 et 54 étaient respectivement des jours-lits inactifs, actifs et strictement hospitaliers. Une enquête a révélé que 65,1% de ces patients (47%) étaient intéressés par des soins à domicile, les préoccupations en matière de sécurité étant la principale raison du désintérêt. Une enquête supplémentaire a révélé que les chirurgiens colorectaux de notre établissement avaient une perception positive de la gestion à domicile pour la diverticulite compliquée, mais avaient des préoccupations concernant l'impact sur leur charge de travail.

Conclusions : La plupart des admissions pour la gestion non opératoire de la diverticulite aiguë compliquée sont dédiées à l'observation et ont le potentiel d'être traitées dans un programme HaD. Le protocole inclut décrit le projet pilote HaD développé pour cette population de patients.

THESIS FORMAT

This thesis is presented in manuscript-based format in compliance with the guidelines and specifications detailed by the Faculty of Graduate and Postdoctoral Studies at McGill University. It includes two distinct manuscripts that are either in preparation or have already been submitted for publication. The first manuscript is a retrospective cohort study that was submitted to the *Journal of the American College of Surgeons*. The second manuscript is the protocol for a pilot study for a Hospital-at-Home program for acute complicated diverticulitis that is being prepared for submission to the *British Medical Journal Open*.

ACKNOWLEDGEMENTS

The completion of this Master's thesis owes its success to the guidance and support of my mentors, supervisors, and colleagues. I am deeply grateful to Dr. Marylise Boutros, who has been an exceptional mentor. Her expertise, both as a surgeon and a clinician researcher, provided the foundation and inspiration for this work. Dr. Boutros' unwavering support has been instrumental in my journey towards completing this thesis, and her mentorship continues to motivate and shape my career aspirations. I am truly inspired by her integrity, dedication, and passion, and I aspire to follow in her footsteps as I pursue my path in surgery.

I would like to extend my heartfelt thanks to Sarah Faris-Sabboobeh and Marie Demian, whose contributions within our research lab have been invaluable. Their assistance, feedback, and dedication to setting up my research projects have played a crucial role in the successful completion of this thesis. Their expertise and willingness to lend a helping hand have been instrumental in shaping my research endeavors. I am also grateful for the support and feedback from the senior surgeons – Dr.'s Nancy Morin, Carol-Ann Vasilevsky, Allison Pang, Gabriela Ghitulescu, and Julio Faria – from the Division of Colorectal Surgery at the Jewish General Hospital.

I would also like to acknowledge my family, who have been a constant source of love and support. To my father, Prof. Rachid Boukhili, your wisdom and encouragement have been a guiding force throughout my academic journey. To my mother, Fatima Atarsia, your unwavering support has provided the strength to overcome challenges. To my siblings, Yesmine and Yanis Boukhili, your companionship and encouragement have been a source of motivation and comfort throughout this academic endeavor.

STATEMENT OF SUPPORT

I would like to recognize the financial support received that allowed me to complete this thesis. I am a recipient of a Canadian Institutes of Health Research (CIHR) Canada Graduate Scholarships – Master's Program award, as well as a Society of American Gastrointestinal and Endoscopic Surgeons (SAGES) General Research Grant. I also received funding from the McGill Surgeon Scientist Program, not only through salary support but also in form of the Surgeon Scientist Program Operational Grant. I would like to recognize the McGill General Surgery Division for supporting my interests in academic surgery and providing me with the necessary time away from clinical duties to pursue a Master's in Surgical and Interventional Sciences during my General Surgery training.

CONTRIBUTIONS TO ORIGINAL KNOWLEDGE

The work presented in this thesis represents original contributions and adds to the body of knowledge in colorectal surgery. This work examines the natural history of acute complicated diverticulitis and clinical outcomes after non-surgical management of these patients. The thesis includes a retrospective cohort study evaluating the proportion of patients managed non-operatively who require minimal inpatient care during their admission and is followed by a comprehensive protocol outlining a pilot study to launch a Hospital-at-Home program to manage these patients. While I have received support from my supervisors and co-authors for each study, the data presented in the following chapters represents my original work.

AUTHOR CONTRIBUTIONS

I have significantly contributed to each of the individual manuscripts listed below, actively participating in study design, data acquisition, data analysis, and manuscript preparation. My contributions were carried out under the supervision of Dr. Marylise Boutros and in cooperation with the co-authors mentioned in each manuscript. A detailed breakdown of the contributions of each individual author for each manuscript is provided below.

Manuscript 1. Non-operative Management of Acute Complicated Diverticulitis: A Retrospective Cohort Needs-Assessment Study for Home-based Management

Study conception: Neyla Boukhili, Sarah Faris-Sabboobeh, Marie Demian, Marylise Boutros

Data acquisition: Neyla Boukhili, Sarah Faris-Sabboobeh, Georgia Rigas

Analysis and interpretation of data: Neyla Boukhili, Natasha Caminsky

Drafting of manuscript: Neyla Boukhili, Sarah Faris-Sabboobeh, Marylise Boutros

Critical revision of manuscript: Neyla Boukhili, Natasha G Caminsky, Sarah Faris-Sabboobeh, Marie Demian, Georgia Rigas, Nancy Morin, Carol-Ann Vasilevsky, Gabriela Ghitulescu, Julio Faria, Allison Pang, Marylise Boutros

Manuscript 2. Protocol for Non-Randomized Feasibility Study of a "Hospital-at-Home" Program for Acute Complicated Diverticulitis

Study conception: Neyla Boukhili, Sarah Faris-Sabboobeh, Marie Demian, Marylise Boutros

Data acquisition: Neyla Boukhili

Analysis and interpretation of data: Neyla Boukhili

Drafting of manuscript: Neyla Boukhili, Sarah Faris-Sabboobeh, Marylise Boutros

Critical revision of manuscript: Neyla Boukhili, Sarah Faris-Sabboobeh, Marie Demian, Marylise Boutros

LIST OF FIGURES AND TABLES

LIST OF ABBREVATIONS

AD – Acute diverticulitis
AUD – Acute uncomplicated diverticulitis
ACD – Acute complicated diverticulitis
CT – Computed tomography
ASCRS – American Society of Colon and Rectal Surgeons
AVOD trial – Antibiotics in the Treatment of Acute Complicated Diverticulitis trial
DIVER trial – Diverticulitis Recurrence trial
IR – Interventional radiology
HaH – Hospital-at-Home
COPD – Chronic obstructive pulmonary disease
COVID-19 – Coronavirus disease of 2019
JGH – Jewish General Hospital
NOM – Non-operative management
PAM – Patient Activation Measure
PA – Patient activation
CCI – Charlson Comorbidity Index
US – United States of America
IRB – Institutional Review Board
BMI – Body mass index
TPN – Total parenteral nutrition
NB – Neyla Boukhili
MB – Marylise Boutros
m^2 – Meter squared
PICC – Peripherally inserted central catheter
ED – Emergency department
SAGES – Society of American Gastrointestinal and Endoscopic Surgeons
Kg – kilogram
CO2 – Carbon dioxide
CHF – congestive heart failure
H – hours
CRS – Colorectal surgery
TN – Transfer nurse

CHAPTER 1 – INTRODUCTION

1.1 Diverticulosis

Diverticulosis is a condition defined by the formation of small protruding pockets – called diverticula – along the large intestine or colon. Colonic diverticula can occur in all segments of the colon but mostly appear in the sigmoid colon – the portion of the colon immediately preceding the rectum – with the second most common site being the right colon. [1] Most individuals with diverticulosis remain asymptomatic throughout life, making the true incidence and prevalence of diverticulosis of the colon difficult to accurately establish. Diverticulosis is strongly associated with advancing age. In fact, the literature states that diverticula are present in over 50% of Americans older than 60 years of age [2]. Despite diverticulosis being traditionally thought of as an ailment affecting only the older population, newer evidence has shown a tendency for increasingly younger people to be afflicted by it in recent years. [3]

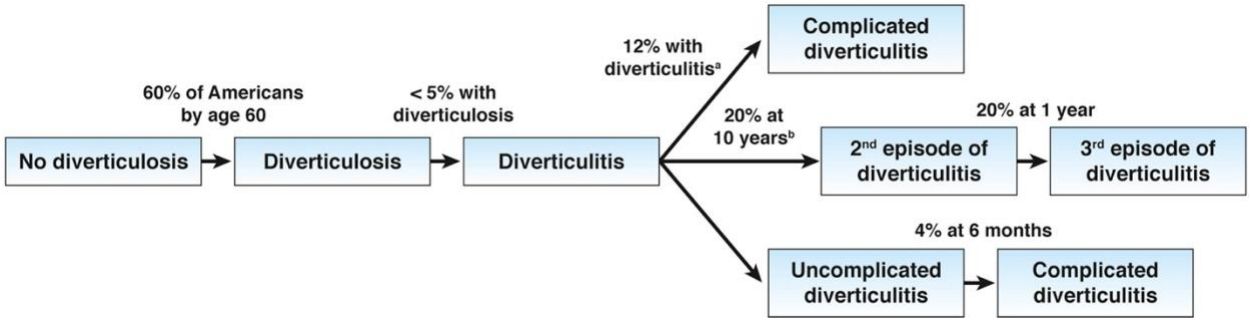


Figure 4: Natural evolution of diverticular disease

It is important to note that the presence alone of these pockets causes no symptom or harm to the patient. In fact, current literature states that under 5% of patients with evidence of

diverticulosis go on to develop diverticulitis. [2] Asymptomatic diverticulosis is typically an incidental diagnosis made on colonoscopy or abdominal imaging performed for other reasons. Diverticular disease is the phrase coined to describe conditions whereby diverticulosis becomes symptomatic and problematic, namely: diverticulitis and diverticular bleeding. For the purposes of this thesis, we will focus on diverticulitis – more specifically, acute complicated diverticulitis.

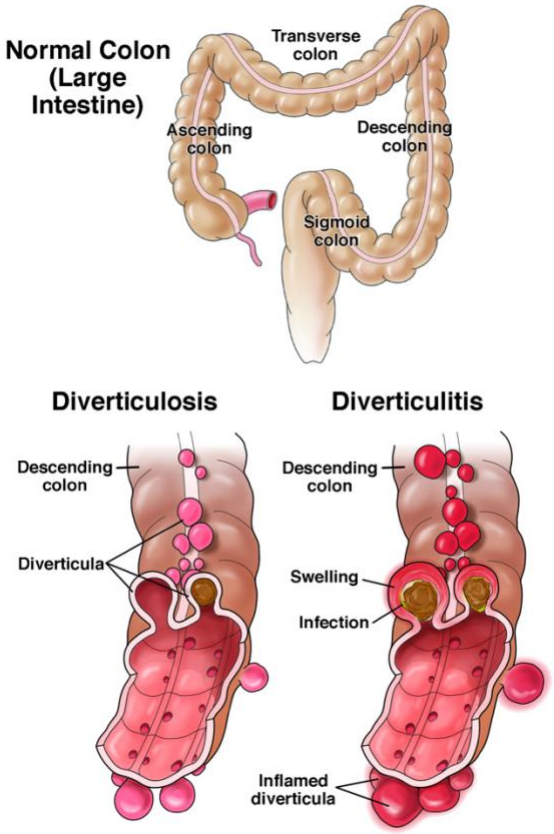


Figure 5: Diverticulosis and Diverticulitis

1.2 Acute diverticulitis

In the United States, acute diverticulitis is the third most common inpatient gastrointestinal diagnosis with approximately 300,000 hospitalizations, resulting in 1.5 million days of inpatient care. [4, 5] Additionally, acute diverticulitis (AD) is one of the most common gastrointestinal diagnoses in outpatient clinics and emergency departments with 1.5-1.9 million outpatient visits each year. [6, 7] AD is an inflammatory condition affecting colonic diverticula, often associated with pericolic inflammation ranging from mild to severe that can be categorized into acute uncomplicated or complicated diverticulitis. [8]

The pathophysiology of acute diverticulitis and the events that trigger the chain reaction causing a benign diverticulum to develop into diverticulitis remain unclear. It was long believed that the pathophysiology of diverticulitis was similar to that of appendicitis: the opening of the pocket blocked by stool in transit in the colon is purported to cause overgrowth and translocation of bacteria that is normally part of the regular colonic flora. This, combined with an increase in pressure, was thought to result in inflammation, microperforation and infection of one or more diverticula and potentially lead to macroperforation. [2] However, recent studies have challenged this theory and suggested instead that the pathophysiology behind diverticulitis may be more akin to that of inflammatory bowel disease, which is to say that the process may be immune-mediated. Some studies have explored the possibility that immune-mediated mechanisms, including abnormal immune responses or autoimmunity, might contribute to the development or exacerbation of diverticulitis. However, the exact mechanisms are still being investigated. [9]

Acute diverticulitis exists on a spectrum ranging from mildly symptomatic acute inflammation of the colon – acute uncomplicated diverticulitis (AUD), to severe life-threatening sepsis due to perforation - acute complicated diverticulitis (ACD). The Hinchey classification,

initially described at McGill University in 1978, was developed to describe intra-operative findings specifically for perforated diverticulitis requiring urgent surgical intervention. [10] Its use has significantly expanded through the years to reflect the key role that computed tomography (CT) abdominal imaging has taken in aiding the diagnosis of acute diverticulitis. [11] The Modified Hinchey classification provides a more specific method of communicating severity of an acute diverticulitis episode than the umbrella terms “uncomplicated” and “complicated” achieve. Under the Modified Hinchey classification, acute uncomplicated diverticulitis is understood to describe Hinchey 0, Ia and Ib disease, where the findings on CT reflect inflammation with possible presence of microperforation. On the other hand, Hinchey II, III and IV are considered to fall under the acute complicated diverticulitis category, which we will elaborate on later in this chapter.

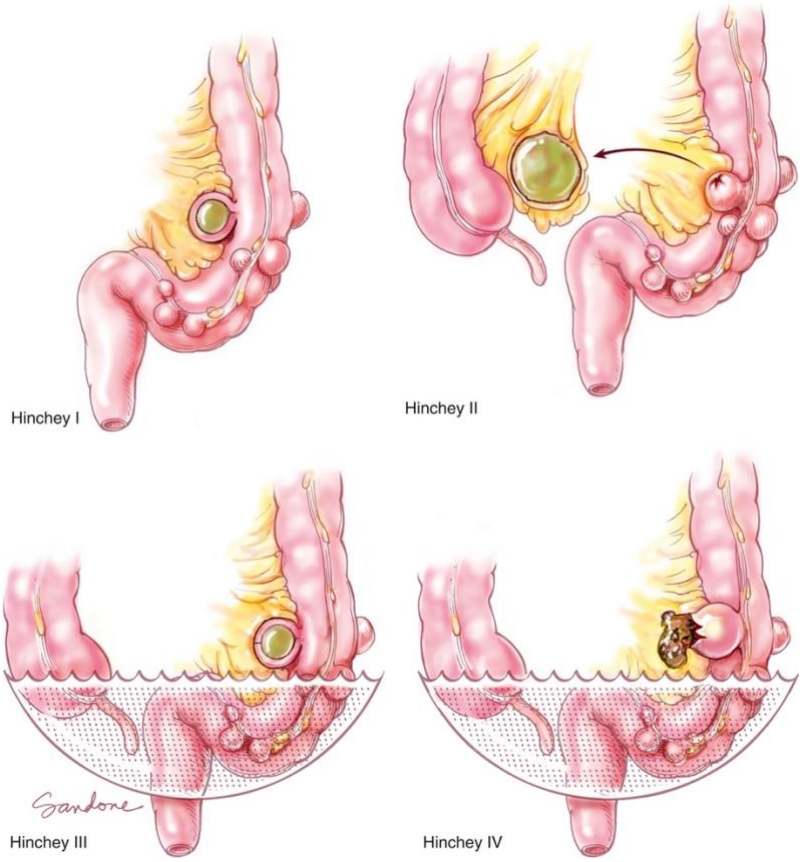


Figure 6: Hinchey Classification for Acute Diverticulitis

Stage	Definition	Associated CT findings
0	Mild clinical diverticulitis ("symptomatic, uncomplicated diverticulitis")	Diverticula, with or without associated colonic wall thickening
Ia	Confined pericolic inflammation, phlegmon	Colonic wall thickening with pericolic soft-tissue changes
Ib	Pericolic or mesocolic abscess	Stage Ia findings plus local abscess
II	Pelvic, distant intraabdominal, or retroperitoneal abscess	Stage Ia findings plus anatomically distinct, distant abscess
III	Generalized purulent peritonitis	Free air with fluid not confined to an abscess cavity; peritoneal wall thickening
IV	Generalized fecal peritonitis	Impossible to distinguish from stage III findings

Table 2: Modified Hinchey Classification for Acute Diverticulitis

1.3 Acute uncomplicated diverticulitis

Management of AUD has changed dramatically in the last ten years, thanks to research that encouraged de-escalation of care. In 1995, the American Society of Colon and Rectal Surgeons (ASCRS) released an initial report of practice parameters to follow for management of AUD. Their recommendations at the time rested on three pillars: intravenous antibiotic therapy, intravenous fluid resuscitation and bowel rest. [12] The AVOD (Antibiotics in the Treatment of

Acute Complicated Diverticulitis) trial conducted in 2012 was a randomized controlled trial that compared the effectiveness of antibiotics versus observation without antibiotics in the treatment of acute uncomplicated diverticulitis, concluding that antibiotics did not offer significant benefits in terms of recovery or outcomes for patients with uncomplicated disease. [13] The DIVER (Diverticulitis Recurrence) trial conducted in 2014 was a subsequent randomized controlled trial that assessed the efficacy of antibiotics in preventing recurrent episodes of uncomplicated diverticulitis, concluding that the use of antibiotics for the index episode did not significantly reduce the risk of recurrence compared to placebo in patients with a first episode of uncomplicated diverticulitis. [14] These studies put in question the use of antibiotics for the treatment of AUD, but more importantly, they introduced to the medical community a new way of understanding, perceiving, and managing AUD by de-escalating care. Thus, in light of the current available evidence we know that patients who present with mild symptoms without signs of systemic infection and who are otherwise healthy are safe to be observed without oral antibiotics, which can subsequently be given in the event of failure to improve without antibiotics. Nowadays, AUD is considered an outpatient disease treatable with oral antibiotics if indicated, with only select cases requiring inpatient observation for pain control or inability to tolerate a diet.

1.4 Acute complicated diverticulitis

1.4.1 Diagnosis, classification, and imaging

In the American Society of Colon and Rectal Surgeons Practice Parameters for the Treatment of Sigmoid Diverticulitis, complicated diverticulitis is defined as diverticulitis associated with peritonitis, abscess formation, fistula, obstruction, or stricture. [15, 16] While it is generally accepted that the presence of fistulae or strictures, whether clinical or radiological, constitute the making of ACD, those features are not described in the Hinchey classification. Both entities require surgical intervention for resolution, though the timing and degree of urgency associated with intervention varies depending on the presenting symptoms, with full colonic obstruction being the most urgent. On the spectrum of disease ranging from acute uncomplicated to complicated diverticulitis, ACD falls under the Hinchey classes II, III, and IV. On CT imaging, Hinchey II disease signifies the presence of colonic inflammation combined with a distinct abscess that is not confined to the primary area of diverticulitis. On the other hand, Hinchey III and IV disease are more difficult to discern on abdominal imaging. The former describes purulent peritonitis i.e. an uncontained, generalized abdominal inflammation with presence of pus that is not confined to an abscess cavity originating from colonic perforation at the site of diverticulitis. The latter describes fecal peritonitis i.e. an uncontained perforation of the affected colon causing gross spillage of fecal content from the colon. On CT imaging, Hinchey III and IV are indiscernible because they both appear as the presence of free air as well as free fluid, not contained to an abscess cavity with peritoneal wall thickening. The management of acute complicated diverticulitis varies immensely as different levels of severity of illness require different considerations, and the paradigm around the need for surgery has shifted considerably over the last decades. Patients presenting with ACD of Hinchey III-IV with peritonitis and critical illness on arrival warrant immediate surgical management, which typically involves removal of the diseased segment of colon, with or without reconnecting the bowel.

1.4.2 Management of acute complicated diverticulitis for patients requiring surgery

As outlined above, the severe presentation of diverticulitis with peritonitis, categorized as Hinchey stages III-IV, underscores the urgency and complexity of treatment, leading us to explore the specific management strategies employed in cases of acute complicated diverticulitis with abscess formation that can lead up to critical illness. The role and timing of surgery in the management of acute diverticulitis has been subject to much change and debate across the last decades. Patients who initially present with Hinchey II ACD with abscesses that fail to respond to intravenous antibiotics alone or combined with percutaneous drainage are then stepped up to surgical management, which also consists of removing the diseased segment of colon. While this thesis will focus on non-operative management of acute complicated diverticulitis, initial surgical management will briefly be addressed, but the role of surgery in the long-term management and counselling is beyond the scope of this work.

The type of surgery performed depends on the patient's condition, the severity and extent of the disease, and whether the surgery is planned or emergent. The two main surgical approaches are primary bowel resection with anastomosis and bowel resection with end colostomy, also known as Hartmann's procedure. Primary bowel resection with anastomosis involves removing the diseased segment of the colon (typically the sigmoid colon, where diverticulitis most commonly occurs) and then reconnecting the healthy end of the proximal colon to healthy rectum. This procedure can be performed with or without a temporary diverting loop ileostomy or colostomy, which diverts stool away from the healing area. The decision to use a stoma is based on factors like the patient's overall health, the severity of the inflammation, and the risk of anastomotic leak. Hartmann's procedure is typically performed in more severe cases,

particularly where there is extensive infection or poor patient health. This involves removing the diseased part of the colon and creating an end colostomy (an opening on the abdomen for the evacuation of feces). The rectal stump is closed off and left inside the abdomen. This procedure is often used in emergency situations and is considered when primary resection with anastomosis carries a high risk. The colostomy may be reversed in a subsequent operation after the patient has recovered.

While ostomies are generally created with the intent of subsequently reversing them, it is important to note that ileostomies and colostomies carry a different profile of morbidity for the patients. In the first surgical option presented, a resection of the bowel with primary anastomosis is undertaken, the surgeon may choose to perform a diverting ileostomy by bringing a segment of small bowel proximal to the anastomosis to the skin surface to divert stool passage away from the fresh connection. In the second surgical option discussed, the colon is brought to the skin surface to evacuate stool since there is no longer bowel continuity with the rectum and anus. The DIVERTI trial published in 2017 showed that in patients undergoing surgery for diverticulitis, the rate of stoma reversal by 18 months after their operation was significantly higher in those undergoing primary anastomosis with diverting ileostomy with a 96% reversal rate, as opposed to only 65% of patients who had a Hartmann procedure being reversed. [17]

Living with an ostomy imposes a significant burden on patients, highlighting the increasing push for de-escalation of care and favoring non-operative management in diverticulitis treatment. Ostomy patients often face physical complications like skin irritation and hernias, alongside profound psychological impacts, including anxiety and altered body image, which can diminish quality of life. These challenges necessitate substantial lifestyle adjustments,

with everyday activities and social interactions becoming sources of stress due to concerns about stoma management and potential ostomy bag issues. The financial implications of ongoing ostomy care add to this burden. Given these considerable challenges, there's a growing emphasis in medical practice on managing diverticulitis non-operatively whenever possible, to avoid the life-altering implications of an ostomy and improve overall patient outcomes. [18-20]

1.4.3 Management of acute complicated diverticulitis with abscess/FA, stable patients

Hemodynamically stable ACD patients with the presence of an abscess are managed in a step-up fashion, with inpatient observation and intravenous antibiotics at the basis of all approaches. While this is typically the extent of management for small abscess under 4 cm, larger abscesses are nowadays often amenable to image-guided percutaneous drainage by Interventional Radiology. [21] Patients with intra-abdominal drains will usually either be discharged home once the abscess cavity has emptied or will be discharged home with the drain in situ with short-term follow-up if drainage remains persistent.

Free air, or free gas, represents an active area of research in the classification of cases of AD. Neither the original nor the modified Hinchey classification consider the presence of extraluminal air in the grading of acute diverticulitis, aside for cases of frank perforation i.e. Hinchey III-IV. There are currently no clear guidelines for the management of patients who are diagnosed with ACD with the presence of pericolic free gas. Free gas, whether pericolic or not, is often considered to be a concerning feature but the necessity to escalate management to surgical intervention has not been supported by evidence thus far. In fact, a study published in 2023 supported the non-operative management of patients with ACD with the presence of free gas on imaging. [22]

The management of stable ACD patients with abscesses or free gas typically involves observation and intravenous antibiotics, without the need for further invasive procedures. This minimalistic approach is well-suited for Hospital-at-Home programs, where such patients can safely receive essential care in the comfort of their homes. By shifting to this model, patients benefit from a familiar environment while healthcare systems efficiently utilize resources and reduce hospital stays.

1.5 Hospital-at-Home

Hospital-at-Home programs (HaH) have been described as early as the 1990s and provide hospital-level care to patients in their own homes. [23] These programs typically involve healthcare professionals visiting patients at home to deliver treatments and monitor their condition, often supported by remote monitoring technology. This approach is designed for patients who require hospital-grade care but do not need the full resources of a hospital ward, offering a comfortable, cost-effective, and safe alternative to traditional hospital stays. They are particularly effective for managing chronic diseases such as heart failure, COPD (chronic obstructive pulmonary disease), and diabetes. These programs have also shown success in post-surgical care, rehabilitation after acute events like strokes, and in treating certain infections requiring intravenous antibiotics. In some cases, they are used for palliative care, providing comfort and support to patients with terminal illnesses in their home environment. This model of care is recognized for reducing hospital readmissions, improving patient satisfaction, and often leading to better health outcomes due to the personalized and continuous nature of care. [24]

The COVID-19 pandemic generated an unprecedented amount of interest for Hospital-at-Home programs, due to the scarcity of hospital beds at the time. At our institution (Jewish General Hospital - JGH), this led to the creation of such programs for patients with cardiopulmonary conditions deemed stable enough to return home with virtual monitoring. To date, the JGH outpatient monitoring programs have had more than 70 medical patients successfully managed in their home. In addition to direct benefits on patients admitted to these programs, such efforts represent a novel avenue to diminish cost and resource usage. [25, 26]

Hospital-at-Home represents an opportunity for patients to receive care in the comfort of their home and diminish the disruption that an in-patient admission can generate in their lives. Patients who have thus far been admitted to Hospital-at-Home programs in our institution have shared generally positive comments including the ease and rapidity of access to a healthcare professional via audiovisual platforms, the improved quality of sleep and accompanying energy levels while at home as well as heightened overall understanding of the condition(s) they were admitted for, having to take a greater part in their care. The potential benefits of HaH for patients span across multiple areas: their quality of life, their sleep hygiene, and the agency they gain in their care to name a few. In addition to direct benefits on patients admitted to Hospital-at-Home, such programs provide a unique opportunity to generate change on a wider population scale both economically and environmentally. Hospital-at-Home programs have been associated with lower costs in the literature at multiple centers were implemented successfully, with up to 19-32% reduction in cost. [25] While HaH programs offer an alternative with many advantages, it is important to recognize that an inadvertent downsides to such hospitalizations, mainly in the form of caregiver strain. When care is shifted from a brick-and-mortar hospital setting to the home, virtual care programs rely on the presence of an informal caregiver, often a family member or

close friend, to facilitate the transition. Literature on this topic remains inconclusive, with a randomized control trial performed in 2014 not finding statistically significant difference in the level of strain on caregivers between a traditional and a HaH admission, while a 2019 qualitative study found HaH programs could contribute to undue strain on the relationship between patient and caregiver. [27, 28]

Patients with acute complicated diverticulitis who present with extraluminal gas or abscesses yet remain hemodynamically stable are prime candidates for Hospital-at-Home management. This patient group often requires monitoring and intravenous antibiotics, but not the extensive resources of a hospital ward. Hospital-at-Home programs have the opportunity to provide these specific interventions in the patient's own home, while aiming to enhancing patients' comfort, sleep and reducing the stress associated with hospital stays. Additionally, this approach has the potential to minimize the risk of hospital-acquired infections and allows for personalized care. The stable nature of these ACD patients, combined with the relatively straightforward management of their condition, makes them well-suited for this innovative and effective care model.

1.6 Thesis Objectives

Despite mounting evidence encouraging the de-escalation of care for acute uncomplicated diverticulitis, such endeavors have not been explored in the management of acute complicated diverticulitis. ACD is still treated as a separate entity from AUD entirely, rather than as a continuation of a spectrum of severity. The objectives of this thesis were three-fold:

a) To evaluate the proportion of admissions for acute complicated diverticulitis that do not require invasive care necessitating inpatient admission;
b) To assess the potential saved hospital bed-days by implementation of home-based management;
c) To develop a Hospital-at-Home program for patients with acute complicated diverticulitis at the Jewish General Hospital.

In pursuit of these objectives, I formulated and executed a retrospective cohort study employing our institutional patient data. This study aimed to ascertain the proportion of patients admitted for acute complicated diverticulitis who necessitated minimal to no invasive interventions in their treatment. Additionally, I sought to identify the proportion of patients suitable for management within a Hospital-at-Home program and the potential amount of saved hospital bed days during the study period. Subsequently, I crafted a comprehensive protocol for the establishment of a Hospital-at-Home program designed to handle cases of acute complicated diverticulitis.

The thesis is structured as follows: Chapter 1 provides background on the epidemiology and pathogenesis of acute diverticulitis, a review of the current literature on the current management strategies used for patients with acute complicated diverticulitis and an introduction to the concept of Hospital-at-Home. Chapter 2 is the retrospective cohort study manuscript, followed by a short Chapter 3 that connects the first manuscript to the second. The protocol for our pilot study comprises Chapter 4. This is then followed by a discussion of the research methods and results in Chapter 5. Finally, Chapter 6 provides the conclusions of the thesis. Inevitably, there will be some degree of repetition throughout the work. Please note that each manuscript

(Chapters 2 and 4) has its own reference list and associated Tables and Figures. The master reference list at the end of the thesis pertains to Chapters 1, 3, and 5 only.

CHAPTER 2 – NON-OPERATIVE MANAGEMENT OF ACUTE COMPLICATED DIVERTICULITIS: A RETROSPECTIVE COHORT NEEDS-ASSESSMENT STUDY FOR HOME-BASED MANAGEMENT (MANUSCRIPT #1)

Neyla Boukhili (M.D.C.M.)[1,2], Natasha G Caminsky (M.D.C.M., M.Sc.)[1,2], Sarah Faris-Sabboobeh (M.Sc.)[2], Marie Demian (M.Sc.)[2], Georgia Rigas[2], Nancy Morin (M.D.)[2], Carol-Ann Vasilevsky (M.D.)[2], Gabriela Ghitulescu (M.D.)[2], Julio Faria (M.D.)[2], Allison Pang (M.D.)[2], Marylise Boutros (M.D.)[2]

[1]Department of Surgery, Division of General Surgery, McGill University Health Centre, Montreal, Quebec, Canada;

[2]Division of Colon and Rectal Surgery, Sir Mortimer B. Davis Jewish General Hospital, Montreal, Quebec, Canada.

Corresponding Author:

Marylise Boutros, MDCM, FRCS(C)

Associate Professor, Department of Surgery, McGill University

Address: Jewish General Hospital, 3755 Cote Ste Catherine, G-317. Montreal, Quebec, H3T 1E2

Tel: (514) 340-8222 (ext. 25996), Email: mboutros@jgh.mcgill.ca

Twitter: @BoutrosMarylise

Abstract

Non-operative Management of Acute Complicated Diverticulitis: A Retrospective Cohort Needs-Assessment Study for Home-based Management

Background: Acute diverticulitis is a significant financial burden in the US, costing $2 billion annually. Despite evidence favoring outpatient management for uncomplicated cases, hospitalizations for complicated cases are on the rise. This study aims to evaluate the suitability of home-based, non-operative management of acute complicated diverticulitis.

Study Design: This was a retrospective cohort study conducted at an academic tertiary care center from 01/2018 – 03/2022. This was followed by patient and surgeon surveys conducted from 02/2023-08/2023. Hemodynamically stable adult patients admitted with acute complicated diverticulitis were included. The primary outcome was the proportion of admissions dedicated to clinical observation and drug administration during which no intervention was performed.

Results: Among 242 admissions, 59 (24.4%) were excluded for critical illness on presentation and the cohort included 183 (75.6%) admissions for non-operative management: 53.6% male with mean age 59.7 ± 14.7 years and Charlson Comorbidity Index 2.2 ± 2.2. Surgical intervention was needed for only 3.3% of patients, while 56.8% received clinical observation and intravenous medications alone. Of 1,066 total hospital bed-days generated: 827, 185 and 54 were idle, active, and strict inpatient bed-days, respectively. A survey found 65.1% of these patients (47%) were interested in home-based care, with safety concerns being the main reason for disinterest. An additional survey found colorectal surgeons at our institution had a positive perception of home-based management for complicated diverticulitis, but had concerns regarding the impact on their workload.

Conclusions: Most admissions for non-operative management of acute complicated diverticulitis are dedicated to observation and have the potential to be treated in a home-care program.

Introduction

The management of acute diverticulitis generates costs of over $2 billion annually in the United States, with 200,000 inpatient admissions and over 2.7 million outpatient visits [1]. The DIVER trial conducted in 2014 confirmed that acute uncomplicated diverticulitis could be safely managed on an outpatient basis with oral antibiotics [2]. Despite these findings, a Danish study conducted in 2018 found that acute uncomplicated diverticulitis (AUD) still made up 83–88% of all hospitalizations, and admissions for acute complicated diverticulitis (ACD) had increased by 42.7% in a 12-year period [3]. Non-operative management of acute complicated diverticulitis (ACD) is an evolving approach in the field of colorectal surgery. Traditionally, surgery has been the standard treatment for ACD, involving the removal of the affected bowel segment. However, in recent years, there has been a paradigm shift towards non-operative management (NOM). This approach typically involves clinical observation, antibiotic therapy, and sometimes interventional radiology (IR) procedures, rather than immediate surgical intervention [4]. Non-operative management is considered when patients with ACD are hemodynamically stable and do not exhibit severe symptoms requiring urgent surgery, including patients with pericolic free air who are often difficult to categorize using the traditional Hinchey classification [5]. This approach offers the potential benefits of reducing the need for surgery, shortening hospital stays, and improving patient outcomes. This study will specifically concentrate on cases of ACD characterized by the presence of abscesses or free air on imaging, with the exclusion of cases with signs of free perforation leading to peritonitis as these are not suitable candidates for non-operative management.

This study aims to evaluate the proportion of admissions for non-operative management of acute complicated diverticulitis that are dedicated to observation and antibiotic administration

alone. The objective of this work is to assess the proportion of admissions for ACD that could potentially be managed with home-based management and inform the development of such a program, including selection of appropriate patients.

Materials & Methods

Study Design

The first part of this study was a retrospective cohort study via medical chart review approved by Institutional Review Board at the Jewish General Hospital (IRB) reported in keeping with the STROBE statement checklist. A short survey was subsequently administered to patients who were admitted for NOM in the study period to assess their interest in home-based management for management of ACD in the event of a recurrence. A separate survey was completed by board-certified colorectal surgeons at our institution to assess their interest as well. Both were reported in accordance with the CROSS statement checklist.

Setting

This retrospective study was conducted at an academic tertiary care center, in Montreal, Canada from January 2018 to March 2022. Follow-up surveys were disseminated between February and July 2023.

Participants

Medical records were obtained for all patients who presented consecutively to the Emergency Room with a diagnosis of acute diverticulitis between January 2018 and March 2022.

Through retrospective chart review of admissions during this time period, we identified patients who were initially managed non-operatively for ACD. ACD was defined as diverticulitis of

Hinchey stages Ib, II, III and IV. The findings associated with these stages include but are not limited to: pericolic inflammation, pericolic phlegmon or abscess, distant intra-abdominal, pelvic or retroperitoneal phlegmon or abscess, or free air/fluid not confined to an abscess cavity. Patients with Hinchey stage Ib were included given frequent need for intravenous antibiosis and inpatient management [6]. Patients were defined as "initial NOM" through chart review if all three of the following criteria were met: (1) hemodynamic stability, (2) tolerance of oral intake, and (3) adequate pain control. Patients were not considered to have undergone initial NOM if they presented to the Emergency Room with peritonitis or other indications for immediate surgery and were thus excluded from the study. The following data was obtained from chart review: (1) demographics (age, gender, height, weight, body mass index (BMI), smoker status, comorbidities, Charleston Comorbidity Index (CCI)) (2) disease characteristics at time of diagnosis (CT findings including location, presence of free air, free fluid and/or abscesses) and (3) clinical presentation (hemodynamic status, laboratory and image findings at admission. Further clinical information obtained from chart review to assess clinical trajectory included: treatment modality, diagnostic and interventional procedures, and length of stay.

Primary Outcome

The primary outcome of interest was the proportion of ACD admissions that were dedicated to clinical observation and intravenous drug administration and during which no additional diagnostic or interventional procedures were performed.

Secondary Outcomes

Secondary outcomes were total hospital bed-days generated by these admissions that were categorized as: *idle-bed days*, *active bed-days*, and *strict inpatient bed-days*. *Idle-bed days* were defined as days spent in hospital dedicated to clinical observation where no diagnostic or

interventional procedures were performed. *Active bed-days* were defined as days where patients underwent diagnostic or interventional radiology (IR) procedures such as: diagnostic imaging, peripherally inserted central catheter insertion, or percutaneous drain insertion. *Strict inpatient bed-days* were defined as days where patients received care exclusive to inpatient wards such as total parenteral nutrition (TPN) or surgery, whether emergent or elective.

Other secondary outcomes that were investigated included length of stay, and characteristics of the diverticulitis episodes.

Patient and Surgeon Surveys

Data pertaining to patient interest in home-based management of ACD was obtained via telephone questionnaire, which was conducted between February and March 2023. Future home-based care capabilities were described (**Appendix 1**) and patients were asked whether they would have considered enrolling in such a program for their admission as opposed to an in-hospital admission for their past episode of ACD and whether they would consider it in the event of a recurrence. Patients who were contacted by telephone and who responded to the questionnaire were included in this subset analysis.

A survey was designed by NB and MB for the board-certified colorectal surgeons at our institution who would be admitting patients to a future home-based ACD program (**Appendix 2**). The survey comprised of 10 questions. The goal of the survey was to explore surgeons' outlook on possible advantages and disadvantages of home-based management of ACD. Surveys were conducted in August 2023 and took approximately 15–20 minutes to perform, either in person or via telephone.

Statistical Analysis

All data analysis was performed using R Studio (R Core Team (2022). R: A language and environment for statistical computing. R Foundation for Statistical Computing, Vienna, Austria.) Statistical significance was defined as p <0.05. Categorical variables were reported as frequency and percentage, while continuous variables were expressed as either mean and standard deviation or median and interquartile range. When indicated univariate analysis of categorical variables was performed using X^2 or Fisher exact test, and Student t- or Kruskall-Wallis test for continuous variables.

Results

Of 242 admissions for ACD during the study period, 59 (24.4%) had peritonitis, hemodynamic instability and/or required urgent surgery upon presentation to the Emergency Department and were thus excluded from the study. As such, the study cohort included 183 (75.6%) admissions that were deemed appropriate for initial non-operative management (**Figure 1**), 53.6% of which were for male patients, with a mean age 59.7±14.7 years, a mean body mass index (BMI) of 28.2 ± 4.9kg/m^2, and mean Charlson Comorbidity Index (CCI) of 2.2 ± 2.2 (**Table 1**).

In this cohort, abdominal imaging showed abscesses in about half of patients admitted for ACD (49.2%) with the majority of these being pericolic rather than distant abscesses (82% pericolic, 18% distant). Extraluminal gas bubbles on imaging were present in nearly half of these patients (47.0%) and followed a similar pattern as abscesses: 79.3% had pericolic gas bubbles, and 20.7% had presence of distant extraluminal gas. Most abscesses were smaller than 5 cm in size (75.6%) and percutaneous drainage was performed for 12.6% of admissions. Of all admissions for ACD that were initially managed non-operatively, only 6 required surgical intervention during their hospitalization (3.3%), with only 1.6% of the cohort requiring emergency surgery for acute

worsening and the rest undergoing semi-elective interventions for smouldering disease (**Table 2**). Only 2 patients (1.1%) required parenteral nutrition during their admission.

Overall, 104 (56.8%) admissions were solely dedicated to clinical observation and intravenous drug administration, and another 72 (39.3%) admissions required either diagnostic or IR procedures. Of 1,066 total hospital bed-days generated by admissions for NOM of ACD: 827, 185 and 54 were *idle*, *active* and *strict inpatient bed-days*, respectively.

Of 183 patients included in the cohort study, 97 were available to be contacted, of which 86 (47%) agreed to participate to a telephone survey. When comparing patients who completed the survey to those who did not, the latter were more likely to be older and more comorbid with a higher CCI, but other sociodemographic factors and characteristics of their admission were not found to be significantly different. (**Table 3**) The mean age of the surveyed group was 54.9 ± 12.3 and 56% were male. Of all respondents, 65.1% would have been interested in receiving their care at home, while 4.7% remained unsure, and 30.2% expressed no interest in home-based management. There were no significant differences in baseline demographic characteristics between patients who expressed interest, or lack thereof, for home-based management for NOM of ACD. Furthermore, we found no significant differences in interest for home-based management when considering whether patients lived alone at the time of admission or whether they needed surgical management of their disease during their index admission (**Table 4**). The reasons mentioned by patients who were not interested in the program included: sentiments that the hospital was a safer option, being more comfortable/familiar with the concept of inpatient hospitalization, and one patient mentioned they were very ill at the time of their admission.

When surveyed, 6 colorectal surgeons at our institutions expressed varying opinions regarding Hospital-at-Home programs for the management of ACD. A significant proportion of

respondents held a favorable view of these programs in general, with 50% indicating a "very favorable" stance and 33% having a "favorable" outlook. Moreover, a similar pattern emerged when assessing the perceived benefits to patients, as half of the surgeons believed that hospital-at-home programs had the potential to be "very beneficial," and an additional 33% deemed them "beneficial" for patients. However, it is noteworthy that a majority of the surveyed surgeons (66%) expressed concerns regarding the potential detrimental impact on their personal workload resulting from the implementation of such a program, while the remaining 33% remained neutral in this regard. Reasons stated for this concern were the need for infrastructure in place to ensure rotating physician coverage for responsibility of patients followed in their home, the possible interference of telecommunications with in-hospital workload, the psychological burden of worrying about patients who cannot be readily examined, and the addition of a new kind of workflow that requires a period of adjustment.

Discussion

The aim of this study was to evaluate the proportion of admissions for non-operative management of ACD that were exclusively dedicated to clinical observation and intravenous drug administration. The underlying goal was to determine the proportion of patients who suffer from ACD who could benefit from home-based management during their admission. Home-based management at our institution was developed during the COVID-19 pandemic and namely serves patients admitted to Internal Medicine for cardiac, pulmonary, and infectious diseases. Current capabilities for home-based management of admitted patients at our institution include, but are not limited to: phlebotomy, intravenous drug administration, diagnostic imaging (X-ray, ultrasound, computed tomography) as well as IR procedures such as percutaneous drain insertion

or placement of PICC lines. To our knowledge, no such program exists for the management of ACD patients.

In our retrospective cohort study, we found that admissions for NOM of ACD generated 827 idle bed-days (78%) during which patients did not undergo any diagnostic or interventional procedures, and a further 185 active bed-days (17%) during which patients underwent either a diagnostic or interventional procedure without requiring surgery or TPN. This accounts for a total of 1,012 bed-days spent in-hospital for treatments that are routinely available within home-based management frameworks at our institution. Of 183 admissions for initial NOM of ACD, same-admission surgery was only performed in 6 instances, and parenteral nutrition was required in 2, which are services that are not amenable to home-based management at our institution.

Of all admissions at our institution for ACD, 75.6% were considered appropriate for initial non-operative management. Nearly all of these (96.7%) would have only required care available via home-based management, including observation, intravenous medication administration, phlebotomy, and/or diagnostic/interventional radiology tests without any reported complication or need for care that would require overnight stay in an inpatient hospital ward.

While the role and timing of surgery for ACD is still being debated, our institutional experience shows that within an appropriately selected patient population for NOM, only a minority (2%) undergo same-admission surgery. In this rare minority, 1.6% required surgery for urgent deterioration and another 1.6% for smouldering diverticulitis. These findings are in line with available literature stating success rates of 92-95% for non-operative management of acute complicated diverticulitis with stable initial presentation [7].

Acute uncomplicated diverticulitis no longer requires admission and further data goes as far as advocating for observation alone without antibiotics in milder cases [2, 8]. Conversely, the

guidelines for acute complicated diverticulitis have been slower to evolve, and current guidelines continue to discuss ACD as a quasi-separate entity instead of a continuation of the spectrum of diverticular disease. While experts encourage de-escalation of care for AUD, our findings may be a first step in exploring a potential more conservative approach for select cases of acute complicated diverticulitis.

Furthermore, upon surveying patients who had been admitted for non-operative management, we found that most patients that we were able to reach would be interested in trialling a home-based management program should they suffer a future episode. Upon surveying colorectal surgeons at our institutions, we found that a significant proportion of them held a favorable view of these programs in general and believed that they had the potential to be beneficial for patients. However, most expressed concerns regarding the potential detrimental impact on their workload resulting from the implementation of such programs.

Despite the rise in popularity of "Hospital-at-Home", "Virtual Care" and home-based programs for various diagnoses in North America, as well as the development of technologies making home- and virtual-based care increasingly available, there is scarcity of evidence objectively assessing and evaluating the need for the implementation of these programs for acute complicated diverticulitis. When comparing our results regarding the number of potentially saved hospital bed-days with the study by Safavi et al (2022) – a feasibility study of Hospital-at-Home care for surgical patients dealing with or undergoing vomiting/nausea, ostomy dysfunction, prostatectomy, laser lithotripsy, laparoscopic colectomy and gastric sleeve – our retrospective study shows a larger number of potentially saved bed-days when pro-rated. This discrepancy is likely due to the nature of both works: the work of Safavi and colleagues described the results from their pilot study, whereas the work presented in this paper represents a

needs analysis for development of such a pilot, specifically for patients suffering from ACD. The observed differences may also be attributable to distinctions in patient populations, with their patients being either in the pre- or postoperative period for elective surgery, whereas most of the patients in our study did not undergo surgery as they were selected for factors that would predispose them for successful non-operative management of ACD.

The strength of this study lies within the novelty of the study question and the design – performing a retrospective study using granular institutional data from the sample of patient who in the future could benefit from a pilot home-based management program, answering the specific question of whether such a program is desirable to begin with. Conversely, the weakness of our results also stems from the study design wherein a prospective cohort study would likely yield more accurate data and the inferences drawn from our results would be significantly more robust. Lastly, an unsurmountable limitation of our study stems from the identification of eligible cases being based on chart review, whereas in practice, clinical judgement and preference of the physician is a significant factor that plays into the decision to opt for NOM as well as the potential decision to enrol patients in home-based care. The survey-based portion of our study opens our results to an important risk of recall bias, as patients who experienced more symptomatic episodes of diverticulitis with longer admissions may be more likely to remember their admissions, which may influence our results. Surveying surgeons for studies can introduce several potential biases, including selection bias as the sample of surgeons surveyed may not be representative of all colorectal surgeons. Response bias was mitigated by the fact that we obtained answers from all board-certified colorectal surgeons at our institution.

We hope to elucidate the limitations described above with the undertaking of a pilot study of home-based non-operative management for acute uncomplicated diverticulitis at our institution, which is currently underway.

Conclusion

Most patients admitted for acute complicated diverticulitis who are hemodynamically stable on presentation can safely be managed non-operatively and require minimal interventional care during their admission. This makes this patient population ideal for home-based management and other such programs providing home- and virtual-based care. About two thirds of patients, when asked, would be amenable to trial such programs. Prospective data is still needed to determine the sociodemographic and clinical factors that would predict success of home-based care for ACD.

References

1. Carr S, V.A., *Colon Diverticulitis.* StatPearls, 2022.
2. Biondo, S., et al., *Outpatient versus hospitalization management for uncomplicated diverticulitis: a prospective, multicenter randomized clinical trial (DIVER Trial).* Ann Surg, 2014. **259**(1): p. 38-44.
3. Hupfeld, L., et al., *Emergency admissions for complicated colonic diverticulitis are increasing: a nationwide register-based cohort study.* Int J Colorectal Dis, 2018. **33**(7): p. 879-886.
4. Francis, N.K., et al., *EAES and SAGES 2018 consensus conference on acute diverticulitis management: evidence-based recommendations for clinical practice.* Surg Endosc, 2019. **33**(9): p. 2726-2741.
5. Tejedor, P., et al., *Management of acute diverticulitis with pericolic free gas (ADIFAS): an international multicenter observational study.* Int J Surg, 2023. **109**(4): p. 689-697.
6. Cameron, J.L. and A.M. Cameron, *Current Surgical Therapy E-Book*. 2019: Elsevier Health Sciences.
7. Dharmarajan, S., et al., *The efficacy of nonoperative management of acute complicated diverticulitis.* Dis Colon Rectum, 2011. **54**(6): p. 663-71.
8. Chabok, A., et al., *Randomized clinical trial of antibiotics in acute uncomplicated diverticulitis.* Br J Surg, 2012. **99**(4): p. 532-9.

Tables and figures

Table 1. Patient characteristics at admission (n=183)

	Mean ± SD; N (%)
Age at admission, years	59.7 ± 14.7
Male	98 (53.6%)
BMI, kg/m^2	28.2 ± 4.91
CCI	2.19 ± 2.15
Smoker	48 (26.2%)
Hypertension	49 (26.8%)
Diabetes mellitus 2	13 (7.1%)
Immunosuppression	14 (7.7%)
Family history of diverticulitis	12 (14%)

Abbreviations: BMI (body mass index), CCI (Charlson Comorbidity Index)

Table 2. Characteristics of admissions for acute complicated diverticulitis (N=183)

	N (%)
Hinchey (%)	
0	2 (1.1%)
IA	90 (49.2%)
IB	74 (40.4%)
II	17 (9.3%)
Phlegmon	26 (14.2%
Abscess	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%)
Semi-elective for failure of resolution	3 (50%)
Urgent for acute deterioration	3 (50%)
Percutaneous drainage	23 (12.6%)

Table 3. Patient characteristics between patient responders and non-responders of survey

Patient characteristics	Responded to survey (*n*=86)	Did not respond to survey (*n*=97)	p-value
Mean age, years (SD)	54.9 (12.3)	63.8 (15.3)	0.00*
Male, N (%)	49 (56.9%)	48 (49.4%)	0.31
Mean BMI (SD)	27.9 (5.1)	28.4 (4.8)	0.62
Mean CCI (SD)	1.5 (1.7)	2.8 (2.3)	0.00*
Hinchey II+, N (%)	82 (95.4%)	88 (90.7%)	0.22
Percutaneous drainage, N (%)	11 (12.8%)	12 (12.4%)	0.93
Underwent surgery, N (%)	3 (3.5%)	3 (3.1%)	0.87

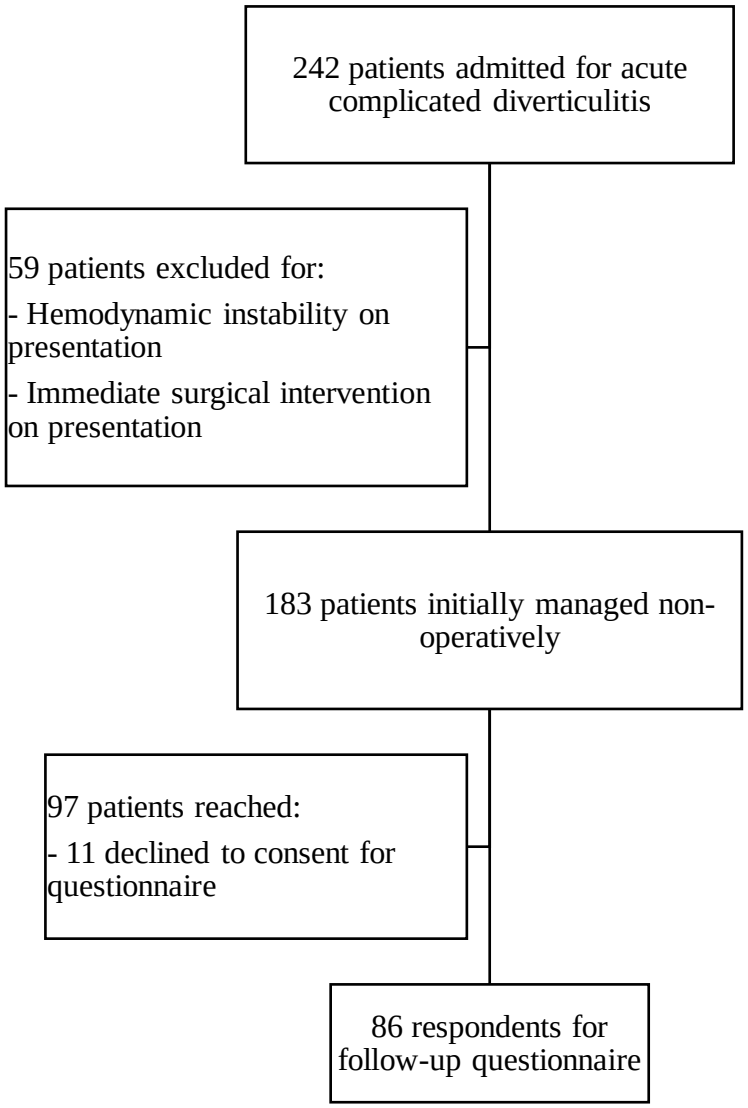
**Clinically significant findings (P-value < 0.05)*
Abbreviations: BMI (body mass index), CCI (Charlson Comorbidity Index)

Table 4. Patient characteristics between interested and not interested in HaH

Patient characteristics	Interested in HaH (*n*=60)	Not interested in HaH (*n*=26)	p-value
Mean age, years (SD)	54.5 (12)	56 (13.1)	0.60
Male, N (%)	11 (42.3%)	38 (63.3%)	0.07
Mean CCI (SD)	1.6 (1.9)	1.3 (1.3)	0.50
Living alone, N (%)	4 (15.4%)	8 (13.3%)	0.80
Underwent surgery, N (%)	1 (3.9%)	2 (3.3%)	0.90

**Clinically significant findings (P-value < 0.05)*
Abbreviations: HaH (Hospital-at-Home), CCI (Charlson Comorbidity Index)

Figure 1. Patient flow diagram



Appendix 1. Patient survey questionnaire

SOCIAL SITUATION

At the time of your admission for diverticulitis, were you employed?

Yes____ No ____

At the time of your admission for diverticulitis, were you living alone?

Yes____ No ____

If not, who were you living with? _____

At the time of your admission for diverticulitis, which of the following best describes your marital status? (circle what word(s) patient identifies)
Single, Living common-law, Married, Separated, Divorced, Widowed

HOSPITAL AT HOME

Since your admission to the hospital for your episode of diverticulitis, we have developed a new program called Hospital-at-Home for acute complicated diverticulitis. As the name says, it is a program whereby we offer hospital care at home for patients needing monitoring and check-ins with the medical team, but who are otherwise well enough that they do not require to stay physically in the hospital. Patients are contacted multiple times a day by their treating physician and nurse via audio or audiovisual platform (telephone or Microsoft Teams), wear a patch on their chest that records their vital signs, and go home with an easy-to-use pump to administer intravenous antibiotics in the comfort of their home. Services that can only be offered in-hospital such as repeat CT scans are expeditiously performed as patients within this program take precedence over patients not admitted to the hospital.

If a Hospital-at-Home program existed at the time of your admission, would you have liked to participate?

Yes ___ No ____ Don't know_____

If not, why? Comments:

SMOKING STATUS

Are you a smoker of tobacco products currently? Yes ___ No ____

If yes:
How many cigarettes per day do you smoke : _____ cigs/day
(or how many cigars or pipe refills…etc)

How long have you been a smoker for? : _____

Were you ever a smoker of tobacco products? Yes ___ No____

If yes:
How many cigarettes per day did you smoke : _____ cigs/day
(or how many cigars or pipe refills…etc)

How long were you a smoker ? _____

When did you quit smoking? _____

RECURRENCE OF DISEASE SINCE ADMISSION

Since your admission or ER visit at the Jewish General hospital for diverticulitis, have you presented to the emergency department at another hospital for problems related to diverticulitis? if "yes," did they tell you that you had a recurrent episode related to your diverticulitis?

Yes____ No ____

Have you undergone any surgery on your colon or intestine at another hospital for problems related to your diverticulitis?

Yes____ No ____

Since your admission at the Jewish General Hospital for diverticulitis, have you presented to any outpatient clinics for problems related to your diverticulitis that required you to receive medication.

Yes____ No ____ If yes how many times : _____

PERSONAL HISTORY OF DIVERTICULAR DISEASE

Prior to your episode in (month, year), had you been diagnosed with any of the following: (circle what word(s) patient identifies)
Diverticular disease : diverticulosis, diverticulitis, "tics"/pockets in intestines

Yes _____ No _____ Don't know_____

Did you require surgery for it: Yes _____ No _____ Don't know _____

Did you require hospital admission for this : yes ___ No ____ Don't know _____

If yes, why? (check all that apply)

Blood found in stool or noticed bleeding from rectum _____
Inflammation (diverticulitis) _____
Abscess (collection of pus) in abdomen _____
Antibiotic treatment given _____
Peritonitis/Perforation _____
Don't know _____

Appendix 2. Surgeon survey questionnaire

1. Roughly what proportion of patients that you admit for complicated diverticulitis require acute operative management of their disease during their admission for a flare?

<5%	5-10%	10-20%	20-30%	30-40%	40-50%	>50%

2. Roughly what proportion of patients that you admit for complicated diverticulitis require operative management of smoldering disease semi-urgently (during index admission or on re-admission for failure of conservative management)?

<5%	5-10%	10-20%	20-30%	30-40%	40-50%	>50%

3. What is your overall opinion of home-based care (Hospital-at-Home) for the management of ACD?

Very unfavorable	Unfavorable	Neither un nor favorable	Favorable	Very favorable

Comments:

4. What are things that would encourage or deter your use of such services?

Answers:

5. How beneficial or detrimental do you think a Hospital at Home program with outpatient services can be to patients?

Very detrimental	Detrimental	Neither detrimental nor beneficial	Beneficial	Very beneficial

6. Depending on above answer, what makes such a program detrimental or beneficial to the patient, in your opinion?

Answers:

7. How beneficial or detrimental do you think a Hospital at Home program with outpatient services can be to surgeons' workload?

Very detrimental	Detrimental	Neither detrimental nor beneficial	Beneficial	Very beneficial

8. Depending on above answer, what makes such a program detrimental or beneficial to surgeons in your opinion?
Answers:

CHAPTER 3 – TRANSITIONING FROM EVALUATION TO IMPLEMENTATION IN ACUTE COMPLICATED DIVERTICULITIS MANAGEMENT

In the previous manuscript, we embarked on a comprehensive evaluation of the management of acute complicated diverticulitis within the context of our institution. Our primary aim was to discern the proportion of patients admitted for this condition who required minimal to no invasive interventions, as well as to identify those individuals who could potentially benefit from a Hospital-at-Home program. This investigation laid the groundwork for our subsequent endeavors, and the results have prompted a deeper exploration into refining the care we provide to this specific patient population.

In the following chapter, we bridge the gap between understanding the needs of patients with acute complicated diverticulitis and the practical implementation of a Hospital-at-Home program tailored to address those needs. Building upon the insights gained from our initial evaluation, we now delve into the realm of designing and implementing a dedicated protocol for Hospital-at-Home care.

Our second manuscript is not merely an extension of the first but represents a pivotal progression in our research journey. We recognized that there exists a subset of patients whose clinical condition may allow for a more patient-centric, home-based approach. Therefore, the objectives shifted from solely understanding the patient population to actively developing a comprehensive protocol that would enable the realization of a Hospital-at-Home program for acute complicated diverticulitis.

This transition from evaluation to implementation is a testament to the dynamic nature of our research. It underscores the importance of bridging the gap between theoretical knowledge and practical application, especially in the context of healthcare. Through the development of a protocol, we aim to not only address the needs of the patients more effectively but also enhance the overall healthcare system's efficiency and resource allocation.

In the upcoming chapters, we will delve into the intricacies of the Hospital-at-Home protocol, detailing the steps, procedures, and guidelines necessary for its successful implementation. This protocol is not just a theoretical construct but a tangible step towards improving patient care and resource management in the realm of acute complicated diverticulitis.

As we navigate this transitional phase, it is our hope that the insights gathered from our evaluation and the practicality of our protocol will collectively contribute to a more patient-centered, efficient, and sustainable approach to managing acute complicated diverticulitis within the Hospital-at-Home framework.

CHAPTER 4 – PROTOCOL FOR NON-RANDOMIZED FEASIBILITY STUDY OF A "HOSPITAL AT HOME" PROGRAM FOR ACUTE COMPLICATED DIVERTICULITIS (MANUSCRIPT #2)

Neyla Boukhili (M.D.C.M.)[1,2], Sarah Faris-Sabboobeh (M.Sc.)[2], Marie Demian (M.Sc.)[2], Nancy Morin (M.D.)[2], Carol-Ann Vasilevsky (M.D.)[2], Gabriela Ghitulescu (M.D.)[2], Julio Faria (M.D.)[2], Allison Pang (M.D.)[2], Marylise Boutros (M.D.)[2]

[1]Department of Surgery, Division of General Surgery, McGill University Health Centre, Montreal, Quebec, Canada;

[2]Division of Colon and Rectal Surgery, Sir Mortimer B. Davis Jewish General Hospital, Montreal, Quebec, Canada.

Corresponding Author:

Marylise Boutros, MDCM, FRCS(C)

Associate Professor, Department of Surgery, McGill University

Address: Jewish General Hospital, 3755 Cote Ste Catherine, G-317. Montreal, Quebec, H3T 1E2

Tel: (514) 340-8222 (ext. 25996), Email: mboutros@jgh.mcgill.ca

Twitter: @BoutrosMarylise

Abstract

Introduction

Hospital-at-Home programs generated interest during the COVID-19 pandemic, leading to the development of a program offering virtual monitoring with increased and facilitated access to outpatient diagnostic and interventional procedures at our institution for patients with cardiopulmonary pathologies. A similar program for management of acute complicated diverticulitis does not yet exist.

Methods & Analysis

Setting & Design: This protocol is for a non-randomized feasibility study that will take place at the Jewish General Hospital, a tertiary care center with six fellowship-trained colorectal surgeons, and it highlights the hospital's experience with Hospital at Home programs, in accordance with CONSORT guidelines. Population: Adult (≥18 years) patients with acute complicated diverticulitis admitted to HaH directly from the ED who do not require immediate surgery and are hemodynamically stable will be included. Intervention: After consenting to participate in our study, participants will wear devices that measure vitals at home and will be contacted by a nurse and physician at least once a day. The HaH intervention will end once patients meet discharge criteria or if they require admission to the hospital. Primary outcome: Feasibility of the HaH program will be defined as 60% of participants *not* requiring unplanned healthcare visits within 30 days of admission to HaH. Secondary outcomes: Readmissions at 60 days, number of saved in-hospital bed-days, cost, and patient satisfaction. Sample size**:** When accounting for the rate of eligible admissions per year and potential success, we estimate an 80%

success in a recruited sample of 30 patients, resulting in a 95% confidence interval of 65.6% – 94.3%.

Ethics & Dissemination

This study received conditional ethics approval in August 2023 from our institution (JGH REB 2023-3557). This study is a recipient of a Society of American Gastrointestinal and Endoscopic Surgeons General Research Grant and Surgeon Scientist Program Research Grant and results will be submitted for publication to their associated medical journal *Surgical Endoscopy*.

Strengths and Limitations of this Study

- The study addresses a significant healthcare cost and resource utilization issue, focusing on the potential benefits of Hospital at Home (HaH) programs for patients with acute diverticulitis.
- Sample size estimation is based on local data and demonstrates a reasonable estimate of success.
- The study is non-randomized, which may introduce selection bias and limit the ability to establish causality.
- The primary outcome measure of 60% success may lack a clear benchmark, as HaH for acute diverticulitis is a novel concept.
- The study is conducted at a single center, limiting generalizability to other healthcare settings.

Introduction

Each year, management of acute diverticulitis costs over $2 billion in the United States, with 200,000 inpatient admissions and over 2.7 million outpatient visits [1]. The DIVER trial conducted in 2014 confirmed that acute uncomplicated diverticulitis could be safely managed on an outpatient basis with oral antibiotics [2]. Most current admissions on the surgical ward for acute diverticulitis at our institution (Jewish General Hospital - JGH), are comprised of patients receiving intravenous antibiotics, of whom a small percentage also undergo percutaneous drainage. Overall, most days spent in hospital during these admissions are not days during which patients are receiving active procedural care.

While Hospital at Home (HaH) programs have successfully been described as early as the 1990s [3], they generated an unprecedented level of interest during the COVID-19 pandemic. At the JGH, this led to the creation of the "COVID@HOME" program, a Hospital at Home (HaH) for patients with COVID-19 seen in the Emergency Department (ED) at the JGH deemed stable enough to return home with a short period of virtual monitoring. While at home, the patient wears a wrist device (similar to a watch), a patch that adheres to the chest, and/or an oxygen saturation probe that regularly measures vital signs [4]. Several times a day, the doctor and nurse contact the patient by phone or on a digital visual platform to check on their progress and the patient can make contact on a 24/7 basis if questions or concerns arise. To date, the JGH HaH program has had more than 50 patients admitted successfully.

In a retrospective cohort study conducted at our institution, we found that 98% of admissions for ACD were for patients requiring intravenous antibiotics, with only 12.6% requiring percutaneous drainage and 3.3% going on to require urgent surgery in the same-

admission [5]. 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. We defined *idle-bed days* as days spent in hospital with no diagnostic/interventional procedures, *HaH-bed days* as days where out-patient procedures available within HaH occurred, and *inpatient bed-days* as days where patients had to physically be in hospital (surgery, total parenteral nutrition). The conclusion that followed was that an HaH program for non-operative management of ACD could have potentially saved 1,012 hospital bed-days during the study period.

Hospital at Home represents an opportunity for patients to receive care in the comfort of their home and diminish the disruption that an in-patient admission can generate in their lives. Patients who have thus far been admitted to Hospital at Home programs in our institution have shared positive feedback including the ease and rapidity of access to a healthcare professional via audiovisual platforms, the improved quality of sleep and accompanying energy levels while at home as well as heightened overall understanding of the condition(s) they were admitted for, and having more ownership of their care. Thus, the potential benefits of HaH for patients span across multiple areas: their quality of life, their sleep hygiene, and the agency they gain in their care to name a few.

In addition to direct benefits for patients admitted to Hospital at Home, such programs provide a unique opportunity to generate change on a wider population scale both economically and environmentally. Hospital at Home programs have been associated with lower costs in the literature at multiple centers where they were implemented successfully, with up to 19-32% reduction in cost [6, 7]. Moreover, virtual home care represents an innovative approach to diminish healthcare-associated carbon footprint caused not only by the utilization of hospital

resources but also via avoided transportation (for patients and their visitors). A recent study has shown that an acute care unit generates 5.5 kg of solid waste and 45 kg CO2 emissions per hospitalization day [8]. When taking into account the findings of our retrospective cohort study, the 1,012 hospital bed-days that could have been avoided with HaH would have amounted to 5,566 kg of solid waste and 45,540 kg of CO2 emissions during our study period, which is equivalent to greenhouse gas emissions from about 15 gasoline-powered passenger vehicles driven for an entire year.

We strive to develop and evaluate a HaH program for patients presenting to the ED with acute complicated diverticulitis (ACD) who require intravenous antibiotics and possible percutaneous drainage. The purpose of this study will be to determine the feasibility and the safety of admission to a Hospital at Home program from the Emergency Department for cases of acute complicated diverticulitis that do not require surgical intervention.

Hypothesis

The overall aim of this study is to determine the success of a novel HaH program at our institution for cases of ACD that do not require immediate surgery on presentation. We hypothesize that a novel HaH program for patients with ACD is safe and feasible, as defined by a success rate of 80% of participants avoiding unplanned healthcare visits within 60 days of their admission. We hypothesize that there will be an improvement in patient satisfaction and that HaH represents a novel avenue to diminish carbon footprint as well as costs related to admissions for acute complicated diverticulitis.

Methods

Study setting

This study will be conducted at the Jewish General Hospital, a tertiary care center with an established Colorectal Surgery practice comprised of 6 fellowship-trained colorectal surgeons. In a retrospective cohort study, we found that there were 242 admissions for acute complicated diverticulitis between January 2018 and March 2022, amounting to approximately 60 admissions for ACD per year.

Hospital at Home is an established resource at our center, which has thus far been used for patients with COPD and CHF, among other diagnoses. The Hospital at Home program works closely with both the Diagnostic and Interventional Radiology departments to secure urgent appointments for HaH patients to undergo imaging or procedures in a timely manner. The HaH nursing team is comprised of 10 nurses who work in shifts to ensure 24h virtual coverage, during which they may be reached audiovisually or via text messages by patients at any moment.

Study design

This protocol is for a non-randomized feasibility study for admission of adult patients with ACD to a HaH program. The study will be reported in accordance with CONSORT guidelines using the 2016 extension for pilot and feasibility studies [9].

Inclusion criteria

Adult (≥18 years) patients with ACD admitted to HaH directly from the ED who do not require immediate surgery and are hemodynamically stable. ACD is defined as acute diverticulitis of Hinchey stage Ib, II, III, and IV. The findings associated with the above include but are not limited to pericolic inflammation and addition of one or more of the following [10]:

1. Pericolic phlegmon or abscess
2. Distant intra-abdominal, pelvic or retroperitoneal phlegmon or abscess
3. Free air or fluid not confined to an abscess cavity

Exclusion criteria

1. Inability to speak/comprehend English/French or give informed consent
2. Unavailable caregiver assistance.
3. Peritonitis or need for urgent surgical intervention.
4. Inability to tolerate a clear liquid diet.

Enrolment

Patients who receive a diagnosis of ACD after seeing an emergency physician (ED MD) will subsequently be assessed by the Colorectal Surgery (CRS) service. If deemed to meet study inclusion criteria, they will then be screened by the HaH Transfer Nurse (TN), who will assess if the patient's social situation is adequate for HaH admission (social support, proficiency with technology, etc.) The decision to enrol a patient to HaH is described in the flowchart in **Figure 1**.

Intervention

After consenting to participate in our study, participants will wear devices (Biobeat™ wrist and/or chest monitors, thermometers) that measure vitals 3 times a day or more, accordingly, while at home. The HaH nursing team is comprised of multiple experienced registered nurses to whom we have given training about the particularities of caring for ACD patients. Participants will be contacted by a nurse via phone or audiovisual platform several times a day (at least three) and by the rounding physician at least once a day with the nurse present as well. They can make contact with the HaH nursing team via phone 24/7 if questions/concerns arise. Diagnostic/therapeutic interventions (e.g. imaging, intravenous antibiotics, percutaneous drainage, etc.) will be arranged, as per standard of care, via priority-reserved outpatient visits. The HaH intervention will end once patients meet discharge criteria or if they require admission to the hospital.

Primary outcome

Feasibility of the HaH program will be defined as 60% of participants *not* requiring unplanned healthcare visits within 30 days of admission to HaH. Unplanned healthcare visits are defined as: visits to the Emergency Department (whether advised by a member of the treating team or not) and unplanned or urgent visits to the Colorectal Surgery clinic that are not part of scheduled patient follow-up. The current literature offers no benchmark of success for HaH for ACD, as this is a novel concept; however, described success rates for HaH for perforated appendicitis and same-day discharge colectomy vary between 57%-70%, from which we estimated a success of 60% [11, 12].

Secondary outcomes

Readmissions at 60 days, number of saved in-hospital bed-days, cost, carbon footprint, and patient satisfaction.

Statistical Analysis

Descriptive data will be reported as means with standard deviations, medians with ranges, or frequencies with proportions. In order to compare patients who succeeded within HaH and those who did not, continuous outcomes will be compared using t-tests or Wilcoxon rank-sum tests and categorical outcomes using $\chi 2$ tests. QoL measures will be analyzed using non-parametric tests (i.e. the Mann Whitney test, the Wilcoxon test or the $\chi 2$ test). If appropriate (adequate sample in the "no success group"), logistic and linear regression models will be used to assess the association of age and diverticulitis severity with HaH success, and the other secondary outcomes.

Sample Size

At our institution, acceptance of HaH has been excellent (>90%) for non-surgical pathologies such as chronic obstructive pulmonary disease (COPD) and congestive heart failure (CHF). In the literature, described success rates for ambulatory management of perforated appendicitis and same-day discharge colectomy vary between 57% to 70% [11, 12], but there is no such data on a Hospital-at-Home program for diverticulitis or similar pathologies.

In the retrospective cohort study conducted at our institution looking at the last 4 years, there were 242 admissions at our institution for acute complicated diverticulitis. We found that 183 of these admissions were potentially eligible for a future HaH program for ACD (approximately 46 admissions per year). Of those, 177 required care entirely available within HaH, demonstrating a

potential success up to 96.7% for Hospital at Home admissions for ACD. From a survey that we completed with patients to gauge interest in a hospital at home program, we estimate that 50% of patients approached for the study will be interested to participate. Thus, when accounting for interest, the rate of eligible admissions per year and potential success, we estimate a 80% success in a recruited sample of 30 patients, resulting in a 95% confidence interval of 65.6% – 94.3%.

Ethics and Dissemination

We have submitted this study to the JGH REB (2023-3557) and it received conditional approval in August 2023. This study is a recipient of a Society of American Gastrointestinal and Endoscopic Surgeons (SAGES) General Research Grant, and results will be submitted for publication to their associated medical journal *Surgical Endoscopy*.

References

1. Carr S, V.A., *Colon Diverticulitis.* StatPearls, 2022.

2. Biondo, S., et al., *Outpatient versus hospitalization management for uncomplicated diverticulitis: a prospective, multicenter randomized clinical trial (DIVER Trial).* Ann Surg, 2014. **259**(1): p. 38-44.

3. Shepperd, S., et al., *Randomised controlled trial comparing hospital at home care with inpatient hospital care. I: three month follow up of health outcomes.* Bmj, 1998. **316**(7147): p. 1786-91.

4. Mietkiewicz, H. *Virtual ward created in patients' homes in pioneering COVID@HOME project*. 2022 [cited 2022 June 3]; Available from: https://jghnews.ciussswestcentral.ca/virtual-ward-created-in-patients-homes-in-pioneering-covidhome-project/.

5. Boukhili, N., Caminsky, N. G., Demian, M., Faris-Sabboobeh, S., Boutros, M., *How can Admissions for Non-operative Management of Acute Complicated Diverticulitis be Successfully Treated Within a Future Hospital-at-Home Program? A Retrospective Cohort Study*, in *American Society of Colon & Rectal Surgeons Annual Scientific Meeting 2023*. 2022.

6. Cryer, L., et al., *Costs for 'hospital at home' patients were 19 percent lower, with equal or better outcomes compared to similar inpatients.* Health Aff (Millwood), 2012. **31**(6): p. 1237-43.

7. Leff, B., et al., *Hospital at home: feasibility and outcomes of a program to provide hospital-level care at home for acutely ill older patients.* Ann Intern Med, 2005. **143**(11): p. 798-808.

8. Prasad, P.A., et al., *Environmental footprint of regular and intensive inpatient care in a large US hospital.* The International Journal of Life Cycle Assessment, 2022. **27**(1): p. 38-49.

9. Eldridge, S.M., et al., *CONSORT 2010 statement: extension to randomised pilot and feasibility trials.* BMJ, 2016. **355**: p. i5239.

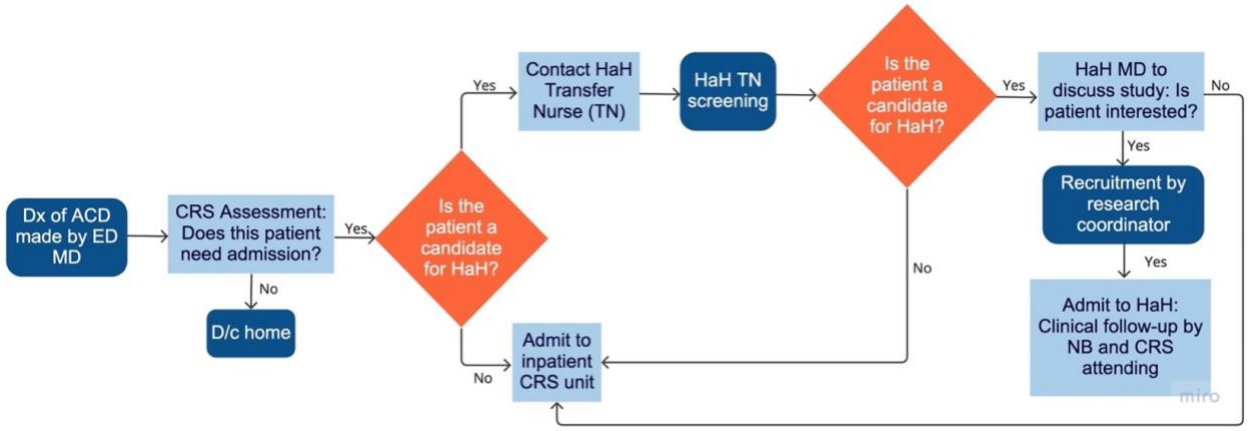
10. Cameron, J.L. and A.M. Cameron, *Current Surgical Therapy E-Book*. 2019: Elsevier Health Sciences.

11. Cabrera López, I.M., et al., *Home-hospital care for children with acute illnesses: A 2-year follow-up study.* J Paediatr Child Health, 2022. **58**(6): p. 969-977.

12. Gignoux, B., et al., *Short-term Outcomes of Ambulatory Colectomy for 157 Consecutive Patients.* Ann Surg, 2019. **270**(2): p. 317-321.

Tables and figures

Figure 1. Patient recruitment flow diagram



Abbreviations: Dx (diagnosis), ACD (acute complicated diverticulitis), ED MD (Emergency Department Physician), CRS (Colorectal Surgery), D/c (discharge), HaH (Hospital-at-Home), TN (transfer nurse), (HaH MD) Hospital-at-Home physician, NB (Neyla Boukhili)

CHAPTER 5 – DISCUSSION

5.1 General Findings

The objectives of this thesis were three-fold: to evaluate the proportion of admissions for acute complicated diverticulitis that do not require invasive care necessitating inpatient admission, to assess the potential saved hospital bed-days by implementation of a Hospital-at-Home program for the management of acute complicated diverticulitis, and to develop such a HaH program for patients with ACD at the Jewish General Hospital.

The first manuscript, a retrospective cohort study, sought to achieve the former two objectives detailed above. It assessed the potential for a Hospital-at-Home program for acute complicated diverticulitis (ACD) by evaluating the proportion of admissions for non-operative management (NOM) dedicated to observation and intravenous antibiotics. In this work, we identified that 75.6% of ACD admissions were suitable for initial NOM, with 96.7% of these potentially manageable at home, with services like phlebotomy and diagnostic imaging. Only a small percentage required same-admission surgery or parenteral nutrition, which are not suitable for home management given our existing institutional capacities. The study found that a significant number of hospital bed-days (1,012 in total) could be saved through Hospital-at-Home management. It also found that the current guidelines for ACD management are evolving slowly, suggesting a need for more progressive approaches.

The study also delved into the perspectives of patients and surgeons regarding the potential implementation of a Hospital-at-Home program for ACD. A survey of patients who had previously been admitted for non-operative management of ACD revealed a strong interest in

participating in a home-based management program for future episodes. This suggests that patients are open to, and possibly prefer, receiving care in the comfort of their own homes as opposed to hospital stays. In parallel, the survey of colorectal surgeons at the institution unveiled a generally positive attitude towards the concept of home-based management programs. Most surgeons recognized the potential benefits such programs could offer to patients, indicating a shift in professional perception towards more flexible, patient-centered care models. However, alongside this positivity, there was a notable concern among surgeons regarding the impact of implementing these programs on their workloads. This apprehension reflects the complexities involved in integrating new care models into existing healthcare systems and the need for careful planning to ensure that such transitions do not adversely affect healthcare providers' workload, efficiency and effectiveness. These surveys provide valuable insights into the acceptability and buy-in of home-based management for ACD from both patient and provider perspectives, highlighting areas of potential support and resistance that would need to be addressed in any future implementation efforts.

Amidst the growing traction of virtual care and the advancement of technologies facilitating its dissemination, there remains a notable gap in robust, objective evidence supporting the implementation of these programs for acute complicated diverticulitis (ACD). When juxtaposing our findings on the potential reduction in hospital bed-days with those from the 2022 feasibility study by Safavi et al.—which examined Hospital-at-Home care for surgical patients experiencing issues like postoperative ileus, high-output ostomies, and undergoing select surgical procedures—our retrospective analysis indicates a greater potential for saving bed-days on a pro-rated basis. This variance can be attributed to the distinct nature of the two studies; Safavi and team's research focused on outcomes from a pilot study, while our study undertakes a needs

assessment for the development of a similar pilot specifically targeting ACD patients. Moreover, the differences might stem from the varying patient demographics: Safavi et al.'s subjects were in pre- or postoperative stages of elective surgeries, whereas our study predominantly included patients chosen for their likelihood of success in non-operative management of ACD, most of whom did not undergo surgery.[29]

The findings outlined above served as a needs-analysis for the development of a non-randomized feasibility study for a pilot Hospital-at-Home program for patients with acute complicated diverticulitis. The protocol outlining the undertaking of the study is included in this thesis as the second manuscript, but no findings can be derived from it.

5.2 Discussion of Methodology

5.2.1 Selection Bias

Selection bias is a concern in the first manuscript included, as is the case with most retrospective cohort studies. The study excluded patients with peritonitis, hemodynamic instability, or immediate surgery needs. This exclusion could introduce selection bias by focusing only on a subset of ACD patients who are stable enough for non-operative management. The results might not be generalizable to all ACD patients, especially those with more severe presentations. However, it is important to note that this is by design, as Hospital-at-Home would not be suitable for those sicker patients. Due to its retrospective design, the study relies on previously recorded data. There's a possibility that the records were not comprehensive or uniformly detailed across all patients, potentially skewing the selection of patients towards those

with more complete medical records. This can bias the findings towards a specific patient profile, in this case towards sicker patients as retrospective chart reviews that rely on completeness of medical charts have been shown to disproportionately include patients with more significant burden of disease, as their records show a tendency to be more complete and fastidiously documented.[30] Furthermore, the design involved surveys of patients and surgeons. While all colorectal surgeons at the institution were surveyed, the patient response rate and the characteristics of those who chose to respond can introduce bias. For instance, patients who had a positive experience with the hospital stay might be more likely to respond, skewing perceptions about the feasibility or desirability of home-based management.

While the second manuscript focuses on the protocol for a non-randomized feasibility study of a pilot Hospital-at-Home program for ACD, there is an unavoidable foreseeable selection bias that may be introduced by the inclusion and exclusion criteria. Similarly to the retrospective cohort study, the feasibility study will select for healthier patients on presentation, as those who present with critical illness and/or need for urgent surgery will not be eligible to participate. Moreover, patients who do not comprehend English or French due to the consenting process, or who do not have a caregiver who can be present in their home are to be excluded for ethical concerns in the consenting process as well as for safety considerations. While necessary, this introduces a risk of selection bias skewed towards patients who have significant social support and away from patients who may belong to more vulnerable patient populations. We hope to address this potential selection bias as feasibility and safety of the program are established and broader inclusion criteria can be utilized, thus improving generalizability of our program.[31]

5.2.2 Unmeasured Confounding

In our retrospective cohort study, we conducted univariate analyses to thoroughly characterize our patient group. However, due to the size of our sample, we did not perform multiple logistic regression analyses to identify differences between patient groups whose admissions solely involved observation and intravenous antibiotics, compared to patient who required percutaneous drainage or surgery. Therefore, it is crucial to recognize potential unmeasured confounding factors that might have affected our results. For instance, patient activation (PA) is a fundamental trait inherent to all patients, encompassing their abilities, knowledge, beliefs, and confidence in managing their health. [32] Patient activation can be evaluated using the 13-item Patient Activation Measure (PAM), which classifies patients into low (level 1, 2) or high activation (level 3, 4). Literature shows that patient populations in which digital health interventions acceptability is high tend to also have higher levels of patient activation.[33] Notably, lower patient activation is associated with prolonged hospital stays in patients undergoing abdominal surgery.[34] If there were variations in PA levels among patients with uneventful and shorter admissions, this could influence the conclusions of our study. It could be speculated that those who sought hospital care earlier in their illness or had shorter stays could have higher activation scores than those with longer hospital stays.

5.2.3 Recall Bias

The first manuscript involved a retrospective cohort study followed by surveys administered to patients who were admitted for non-operative management of acute complicated diverticulitis. Since these surveys were conducted years after the patients' hospital admissions (between February and March 2023 for a cohort from January 2018 to March 2022), there is a substantial risk of recall bias. Patients might not accurately remember their symptoms, their level

of discomfort, or their attitudes and thoughts during their hospital stay. This is particularly relevant for subjective experiences like pain levels, tolerance of oral intake, and interest in home-based management.[35] Similarly, the surveys completed by surgeons assessing their outlook on home-based management could be subject to recall bias. Surgeons might not accurately remember specific cases, their own decision-making processes, or their attitudes towards non-operative management at the time. The study's objective to assess the proportion of admissions for ACD that could be managed with home-based management relies on the retrospective opinions of patients and surgeons. Their current attitudes or beliefs could be influenced by their experiences or developments in the field since their original involvement with the cases in question. This could lead to an overestimation or underestimation of the suitability or desirability of home-based management.

5.3 Future Directions

As of now, the pilot study has successfully obtained ethics approval and has already enrolled 10 patients after screening 22. These initial stages of implementation provide a wealth of information, both in terms of operational challenges and patient outcomes. Preliminary descriptive results show that this cohort of patients is relatively young and healthy, with a mean age of 56 $\pm$ 9.3 years and a mean Charlson Comorbidity Index (CCI) or 1.6 $\pm$ 1.4. The patterns of disease were similar to patients included in our retrospective cohort study, with most patients displaying presence of abscess, phlegmon, and/or extraluminal gas on diagnostic imaging. Among the 10 patients enrolled, 6 seamlessly progressed through the program. Two participants were judiciously transitioned to inpatient care following an evaluation that indicated a need for

treatment beyond non-operative management. This transition aligns with the program's design, which anticipates and accommodates such escalations as a standard aspect of patient care progression. Unfortunately, the remaining two patients did not successfully complete the Hospital-at-Home (HaH) pathway, as evidenced by their unscheduled visits to the Emergency Department within 7 days post their virtual discharge from HaH. Considering these outcomes, we determined our program's success rate thus far to be 80%. This rate adheres to our predefined success criterion, which includes maintaining a minimum 60% rate of patients not requiring unplanned healthcare interventions within a 30-day period following discharge. These preliminary results offer insights into the practicality of the program and patient compliance. Early indicators suggest a positive response to home-based care, with patients expressing appreciation for the comfort and familiarity of their own homes during treatment. This observation aligns with the survey responses highlighted in the first manuscript, where a strong patient interest in home-based management was noted. Enrollment is actively ongoing and will continue until the target sample size is achieved. Additionally, pending tasks include conducting telephone follow-ups to complete satisfaction surveys, as well as performing a comprehensive cost analysis.

Future directions of this research involve completion and comprehensive evaluation of this pilot program. Key areas of focus will include the effectiveness of the HaH program in managing ACD, patient safety, readmission rates, and overall patient and caregiver satisfaction. Additionally, the economic impact of such a program on the healthcare system, in terms of cost-saving and resource allocation, will be a crucial aspect of this analysis. Furthermore, it will be important to expand the scope of the study to include a more diverse patient population, with the help of our diverse team of healthcare provider, professional interpretation services, and

broadened inclusion social criteria once the program is deemed safe and feasible for our initial cohort. This expansion will help address potential selection biases identified in the initial studies and ensure that the program is accessible and applicable to a broader range of patients, including those from different socio-economic backgrounds and with varying levels of social support.

Moreover, as more patients are enrolled and more data is collected, the study will aim to conduct a robust statistical analysis. This will involve not only descriptive statistics but also inferential methods to better understand the effectiveness and efficiency of the HaH model for ACD patients. The use of predictive analytics such as risk stratification models to predict which ACD patients are most likely to benefit from HaH, alerts for early intervention and patient satisfaction predictors will help identify patients who would most benefit from such a program and constitutes a prospective area of research.

In addition, qualitative research methods, such as patient and caregiver interviews as well as healthcare practitioner interviews, may be employed to gain deeper insights into the experiences of those involved in the HaH program. These qualitative studies will complement the quantitative data, providing a holistic understanding of the program's impact.

Lastly, based on the findings from the pilot study, modifications, and improvements to the HaH program will be considered. This iterative process will involve feedback from all stakeholders, including patients, caregivers, healthcare providers, and administrative staff, to ensure that the program is patient-centered, efficient, and sustainable in the long term. The preliminary success of the pilot program and the future research directions outlined above signify a promising step towards innovative, patient-centered care models for managing acute complicated diverticulitis. The ongoing study will continue to shed light on the feasibility, effectiveness, and broader implications of Hospital-at-Home programs in modern healthcare

systems in the endeavour of de-escalating care for patients suffering from acute complicated diverticulitis.

CHAPTER 6 – CONCLUSION

The majority of patients presenting with hemodynamic stability upon admission for acute complicated diverticulitis can be effectively managed through non-operative approaches, necessitating minimal intervention throughout their hospital stay. This attribute positions them as prime candidates for home-based management schemes, including Hospital-at-Home programs that incorporate both home and virtual care modalities. Surveys indicate that approximately two-thirds of patients are receptive to participating in such innovative care programs. Nonetheless, there remains a need for prospective data to elucidate the sociodemographic and clinical predictors of successful outcomes in home-based care models for ACD and to identify challenges in implementation. This information is crucial for optimizing patient selection and enhancing the efficacy of these programs. A non-randomized feasibility study of a pilot Hospital-at-Home program for acute complicated diverticulitis is currently in progress, aiming to address these queries. This ongoing study is expected to provide valuable insights in the de-escalation of care for acute complicated diverticulitis.

THESIS REFERENCES

1. Golder, M., et al., *Demographic determinants of risk, colon distribution and density scores of diverticular disease.* World J Gastroenterol, 2011. **17**(8): p. 1009-17.
2. Strate, L.L. and A.M. Morris, *Epidemiology, Pathophysiology, and Treatment of Diverticulitis.* Gastroenterology, 2019. **156**(5): p. 1282-1298.e1.
3. Faria, G.R., et al., *Acute diverticulitis in younger patients: any rationale for a different approach?* World J Gastroenterol, 2011. **17**(2): p. 207-12.
4. Kozak, L.J., C.J. DeFrances, and M.J. Hall, *National hospital discharge survey: 2004 annual summary with detailed diagnosis and procedure data.* Vital Health Stat 13, 2006(162): p. 1-209.
5. Peery, A.F., et al., *Burden of gastrointestinal disease in the United States: 2012 update.* Gastroenterology, 2012. **143**(5): p. 1179-1187.e3.
6. Peery, A.F., et al., *Burden and Cost of Gastrointestinal, Liver, and Pancreatic Diseases in the United States: Update 2018.* Gastroenterology, 2019. **156**(1): p. 254-272.e11.
7. Shaheen, N.J., et al., *The burden of gastrointestinal and liver diseases, 2006.* Am J Gastroenterol, 2006. **101**(9): p. 2128-38.
8. Jacobs, D.O., *Clinical practice. Diverticulitis.* N Engl J Med, 2007. **357**(20): p. 2057-66.
9. Schieffer, K.M., et al., *RNA-seq implicates deregulation of the immune system in the pathogenesis of diverticulitis.* Am J Physiol Gastrointest Liver Physiol, 2017. **313**(3): p. G277-g284.
10. Hinchey, E.J., P.G. Schaal, and G.K. Richards, *Treatment of perforated diverticular disease of the colon.* Adv Surg, 1978. **12**: p. 85-109.
11. Kaiser, A.M., et al., *The management of complicated diverticulitis and the role of computed tomography.* Am J Gastroenterol, 2005. **100**(4): p. 910-7.
12. Roberts, P., et al., *Practice parameters for sigmoid diverticulitis. The Standards Task Force American Society of Colon and Rectal Surgeons.* Dis Colon Rectum, 1995. **38**(2): p. 125-32.
13. Chabok, A., et al., *Randomized clinical trial of antibiotics in acute uncomplicated diverticulitis.* Br J Surg, 2012. **99**(4): p. 532-9.
14. Galli, R., et al., *[Changes in indications for surgery in the management of diverticulitis].* Ther Umsch, 2014. **71**(12): p. 727-36.
15. Feingold, D., et al., *Practice parameters for the treatment of sigmoid diverticulitis.* Dis Colon Rectum, 2014. **57**(3): p. 284-94.
16. Hall, J., et al., *The American Society of Colon and Rectal Surgeons Clinical Practice Guidelines for the Treatment of Left-Sided Colonic Diverticulitis.* Dis Colon Rectum, 2020. **63**(6): p. 728-747.
17. Bridoux, V., et al., *Hartmann's Procedure or Primary Anastomosis for Generalized Peritonitis due to Perforated Diverticulitis: A Prospective Multicenter Randomized Trial (DIVERTI).* J Am Coll Surg, 2017. **225**(6): p. 798-805.
18. D'Ambrosio, F., et al., *Peristomal Skin Complications in Ileostomy and Colostomy Patients: What We Need to Know from a Public Health Perspective.* Int J Environ Res Public Health, 2022. **20**(1).

19. Zhang, Y., et al., *Relationship between psychosocial adaptation and health-related quality of life of patients with stoma: A descriptive, cross-sectional study.* J Clin Nurs, 2019. **28**(15-16): p. 2880-2888.
20. LeBlanc, K., et al., *The Financial Impact of Living in Canada With an Ostomy: A Cross-sectional Survey.* J Wound Ostomy Continence Nurs, 2019. **46**(6): p. 505-512.
21. Cameron, A., Cameron JL., *Current Surgical Therapy*. 13th ed. 2020: Elsevier.
22. Tejedor, P., et al., *Management of acute diverticulitis with pericolic free gas (ADIFAS): an international multicenter observational study.* Int J Surg, 2023. **109**(4): p. 689-697.
23. Shepperd, S., et al., *Randomised controlled trial comparing hospital at home care with inpatient hospital care. I: three month follow up of health outcomes.* Bmj, 1998. **316**(7147): p. 1786-91.
24. Levine, D.M., et al., *Hospital-Level Care at Home for Acutely Ill Adults: A Randomized Controlled Trial.* Ann Intern Med, 2020. **172**(2): p. 77-85.
25. Cryer, L., et al., *Costs for 'hospital at home' patients were 19 percent lower, with equal or better outcomes compared to similar inpatients.* Health Aff (Millwood), 2012. **31**(6): p. 1237-43.
26. Leff, B., et al., *Hospital at home: feasibility and outcomes of a program to provide hospital-level care at home for acutely ill older patients.* Ann Intern Med, 2005. **143**(11): p. 798-808.
27. Rossinot, H., O. Marquestaut, and M. de Stampa, *The experience of patients and family caregivers during hospital-at-home in France.* BMC Health Serv Res, 2019. **19**(1): p. 470.
28. Utens, C.M., et al., *Informal caregiver strain, preference and satisfaction in hospital-at-home and usual hospital care for COPD exacerbations: results of a randomised controlled trial.* Int J Nurs Stud, 2014. **51**(8): p. 1093-102.
29. Safavi, K.C., et al., *Hospital at Home for Surgical Patients: A Case Series From a Pioneer Program at a Large Academic Medical Center.* Ann Surg, 2022. **275**(1): p. e275-e277.
30. Rusanov, A., et al., *Hidden in plain sight: bias towards sick patients when sampling patients with sufficient electronic health record data for research.* BMC Med Inform Decis Mak, 2014. **14**: p. 51.
31. Rothman, K.J., S. Greenland, and T.L. Lash, *Modern epidemiology*. 2008, Wolters Kluwer Health/Lippincott Williams & Wilkins Philadelphia: Philadelphia.
32. Hibbard, J.H., et al., *Development of the Patient Activation Measure (PAM): conceptualizing and measuring activation in patients and consumers.* Health Serv Res, 2004. **39**(4 Pt 1): p. 1005-26.
33. Marvel, F.A., et al., *Digital Health Intervention in Acute Myocardial Infarction.* Circ Cardiovasc Qual Outcomes, 2021. **14**(7): p. e007741.
34. Dumitra, T., et al., *Association Between Patient Activation and Health Care Utilization After Thoracic and Abdominal Surgery.* JAMA Surg, 2021. **156**(1): p. e205002.
35. O'Brien, B., et al., *Recall, response bias and recognition are differentially impacted by social anxiety irrespective of feedback modality.* J Behav Ther Exp Psychiatry, 2022. **74**: p. 101694.