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Tala Al-Saghir

Wayne State University School of Medicine, Detroit, fz9400@wayne.edu

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Lack of alternatives to colonoscopy limits care of patients unable to complete bowel preparation

TALA AL-SAGHIR, BS, Wayne State University School of Medicine, fz9400@wayne.edu

ABSTRACT A clinical decision report using:

Benech N, Vinet O, Gaudin JL, et al.: The ONECC Study Group. Colon capsule endoscopy in clinical practice: lessons from a national 5-year observational prospective cohort. *Endosc Int Open*. 2021;9(10):E1542-E1548. <https://doi.org/10.1055/a-1526-09231>

for a patient with incomplete bowel preparation and colonoscopy.

Keywords: *incomplete colonoscopy, incomplete bowel preparation, imaging, alternatives*

Clinical-Social Context

Mr. Leon Hudson (pseudonym) is a 52-year-old Black man who presented to our quaternary care community emergency department due to a hemoglobin count of 6.3, as reported to him by his dialysis center. His symptoms included fatigue, shortness of breath with exertion, and three days of bloody and tarry black stools. Upon further investigation, it was found that the patient had been admitted to the hospital numerous times in the past year due to his relapsing anemia. The patient's clopidogrel, the original reason for prescription unknown to the patient and not included in his health records, was immediately discontinued. He was scheduled for esophagogastroduodenoscopy (EGD) and colonoscopy with the gastrointestinal (GI) team to assess for a source of lower GI bleed. During his wait for his scheduled colonoscopy, Mr. Hudson's hemoglobin continued to drop and he was transfused with 3 units of blood.

Mr. Hudson was started on nothing by mouth (NPO) at midnight and began his bowel preparation with ethylene glycol at 3AM the night before the procedure. The next morning, upon evaluation, his stool was still brown in color and deemed unprepared. The procedure was rescheduled for the next day. That same day, Mr. Hudson was put on a clear-liquid-only diet and restarted his bowel preparation, and went NPO at midnight. He woke up the next day with his preparation still incomplete. Although Mr. Hudson had been fully compliant with the bowel preparation process, for unknown reasons, this same pattern of bowel preparation and then failure went on for 7 days.

Despite the discomfort of the bowel preparation process, the frustration of being kept in the hospital for so long, and feeling despondent about being away from his wife, Mr. Hudson remained amiable and amenable to the care team's wishes. During this time frame, his EGD was successfully completed and showed no signs of bleeding. Eventually, due to the desire for answers and action, the GI team along with Mr. Hudson decided to complete his colonoscopy even though his preparation continued to be incomplete. Mr. Hudson's preparation was considered inadequate upon colonoscopy, his lower GI tract was poorly visualized, and no source of bleeding was identified.

TALA AL-SAGHIR, BS, is a medical student at Wayne State University School of Medicine.



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Despite the low confidence in this assessment, after multiple conversations between Mr. Hudson and his care teams, it was decided that no additional testing would be done.

Mr. Hudson has an extensive medical profile, including but not limited to a history of essential hypertension, type 2 diabetes mellitus, transient ischemic attack, morbid obesity, obstructive sleep apnea, end stage renal disease (ESRD) on hemodialysis, and chronic anemia requiring multiple transfusions in the past year due to suspected GI bleed. His anemia has remained uncontrolled in the past year and is further exacerbated by his ESRD. His dialysis appointments on Tuesday, Thursday, and Saturday take up a significant portion of his week and make it difficult for him to schedule other doctor's appointments to follow up for his chronic health conditions. Mr. Hudson is a poor historian for his past medical history and medication regimen due to poor health literacy. With that being said, he is curious about his medications and is an active listener when the care team discusses his treatment. He lives at home with his wife who is his primary caretaker and assists him with dialysis visits and doctor's appointments. The patient is covered by Medicaid insurance and is able to receive all work up necessary during his inpatient stay, at no additional costs.

Clinical Question

What are alternatives for bowel visualization when bowel preparation and resultant colonoscopy are deemed incomplete?

Research Article

Benech N, Vinet O, Gaudin JL, et al.: The ONECC Study Group. Colon capsule endoscopy in clinical practice: lessons from a national 5-year observational prospective cohort. *Endosc Int Open.* 2021;9(10):E1542-E1548. <https://doi.org/10.1055/a-1526-09231>¹

Description of Related Literature

The literature review began with a PubMed search of: (diagnostic colonoscopy) AND (incomplete bowel preparation) AND (alternative). The search strategy is aimed at identifying studies that evaluate the usage of diagnostic colonoscopies for high grade GI bleed detection, not just the more commonly used screening colonoscopy for colorectal cancer (CRC) detection. This search yielded 19 results and no filters were used. On assessment, 13 sources were excluded. The studies conducted by Arnesen et al., Sosna et al., Loftus et al., Leaper et al., and Sohns et al. did discuss alternatives to colonoscopy, but only within the specific context of colorectal tumor detection, not taking into account other results, and were thus excluded. Gustafsson et al. and Poon et al. were out of scope, focusing on alternative methods for bowel preparation, not imaging. Ratnasingham et al. studied the use of colonoscopy in constipated patients and Sanaka et al. discussed the effect of colonoscopy timing on successful imaging. While these are related to colonoscopy, they propose no imaging alternatives for patients with incomplete preparation. Chou et al. studied reasons for incomplete flexible sigmoidoscopy, Luz et al.'s study was only available in German, Burling et al. explored the availability of CT colonography services, and Goerg et al. studied probiotic therapy in pseudomembranous colitis. These articles were irrelevant to the clinical question and thus deemed out of scope and excluded from the literature review. The remaining 6 articles were reviewed in detail below. An additional 5 articles relating to the scenario were also reviewed due to their relevance outside of the search strategy, also reviewed in detail below.

Villa et al. conducted a meta-analysis that emphasizes the importance of adequate bowel preparation, patient sedation, and patient positioning for colonoscopy completion.² The article goes on to discuss interventions such as balloon-assisted colonoscopy in patients with difficult anatomy, CT or MR colonography in patients who must be able to complete "vigorous bowel preparation," and new technology such as the colon capsule. While all are viable options for incomplete colonoscopy, balloon-assisted colonoscopy does not address the issues of incomplete preparation, the CT and MR colonography exclude patients unable to complete preparation, and the colon capsule is not yet widely accessible in the hospital setting.

Hussey et al. conducted a prospective single center study in which same day colon capsule endoscopy (CCE) was conducted immediately after an incomplete colonoscopy.³ The CCE provided diagnostic imaging in segments unexplored by the colonoscopy for 74% of the patients, with 26% requiring changes in management due to findings. While this indicates that CCE has clinical power, the



study excluded patients from the CCE trial who had failed their initial colonoscopy due to obstruction or inadequate preparation making the study limited in its patient population inclusion criteria. This is supported by the fact that only 50 same day cases were completed in the two years that the study was conducted, a small sample size for the indicated time frame.

Riccioni et al. explores the feasibility of PillCam colon capsule endoscopy (PCCE) as a replacement for colonoscopy in clinical practice.⁴ While the study does ascertain that PCCE can be utilized as a second line when a colonoscopy is unable to provide conclusive results, the majority of the research focuses on the capsule's ability to detect CRC and its feasibility as a replacement for golden standard colonoscopy. The study was mildly expanded to discuss its clinical implications on irritable bowel disease diagnoses, but failed to take into account other pathologies commonly identified on colonoscopy screening.

Wehrmann et al.'s prospective study compares the efficacy of classic colonoscope vs routine upper GI scope extended to the cecum for colonoscopy use.⁵ The study found that upper GI scopes, as a backup for failed standard colonoscope cecal intubation, resulted in 79% success rate of cecal intubation. Rather than an alternative, this proposes an adjuvant imaging modality for successful colonoscopy imaging. The findings are fortified by the use of a single investigator for the procedure. While the study does identify 650 patients, all patients who were unable to successfully complete bowel preparation were excluded, making the study limited in its diversity of clinical application.

Alarcón-Fernández et al. analyzed the use of colon capsule endoscopy (CCE) as a guide for medical decision making in patients unable to complete routine colonoscopy via a prospective study.⁶ Although the study discussed the effect of different levels of bowel preparation on capsule visibility, it was limited due to its exclusion of 78.52% of the patients from the CCE study if they were unable to complete a preliminary colonoscopy due to "poor" bowel cleansing. CCE readings were furthermore only considered conclusive, and thus successful, if all segments of the bowel had "good" or "excellent" cleansing. This limited the study in that only 65% of the 45 eligible patients were able to meet this criterion, excluding another large portion of the patients from the study.

The chosen study by Benech et al. is a prospective national cohort study conducted in France to assess the efficacy of CCE as an alternative to classic colonoscopy screening.¹ Unlike other studies, this study directly assesses clinical application of CCE rather than just practical feasibility. A large population of 689 patients were identified, adding to the power of the study and clinical relevance, and CCE was selectively performed on patients with contraindications to colonoscopy or anesthesia. Adequate bowel preparation was not a criterion for the study, and of the 689 CCE's performed, only 48.9% were completed and performed on patients with adequate bowel preparation. Real-life practical efficacy of CCE compared to colonoscopy were assessed via long and short term follow up with the selected patients over a 5-year period.

Havshoi et al. conducted a prospective cohort study comparing the efficacy of CCE to CT colonography following incomplete colonoscopy and anesthesia-assisted colonoscopy.² Efficacy was defined as completion rate and polyp detection rate (PDR). The study found that although PDR of CCE had high sensitivity, CCE completion rates were quite low. However the study is limited by the data size with only 65 patients, 36 of whom underwent CCE as an alternative to CT colonography, 27 as an alternative to anesthesia-assisted colonoscopy. This limits our ability to apply results widely. Additionally, patients with poor bowel preparation were deemed not eligible for CCE, making this study inapplicable to our study.

Nogales et al. conducted a study exploring CCE as an alternative to repeat colonoscopy in patients that underwent primary incomplete colonoscopy.⁸ Patients had incomplete colonoscopies primarily due to inability to move past a bowel loop using standard maneuvers; the remaining patients were unable to complete their primary colonoscopy due to anatomical issues. With CCE, 71.9% of the patients achieved full visualization. Of the 27 patients who did not achieve full visualization with CCE, it is estimated that with colonoscopy they would be able to achieve complete visualization of the colon in 92.7% of the cases. While this presents an important area of discussion, it is limited in that it does not include patients who have incomplete colonoscopy due to incomplete bowel preparation.

Cash et al.'s prospective, randomized study compares CRC detection in classic colonoscopy, CCE, and CT colonography.⁹ The efficacy of these methods were measured by their ability to detect polyps greater than 6 mm. While less efficacious than classic colonoscopy, CCE was found to be superior to CT colonography as a CRC screener. This study is limited in that it does not assess the efficacy of these methods in patients who had initially failed colonoscopy, they were solely assessed as alternatives for the general

population. Additionally, their primary end-point was to find an alternative for CRC screening, excluding other pathologies such as GI bleed.

The field consists of good quality patient oriented evidence and earns a SORT grade of A.¹⁰

Critical Appraisal

Benech et al. conducted a prospective national cohort study in France assessing the efficacy of CCE as a replacement for classic colonoscopy in patients predominantly with contraindications to sedation or technical limitation for successful imaging.¹ CCE has been widely suggested as a replacement for colonoscopy due to high sensitivity of polyp detection, as seen in previous studies. Benech et al.'s study had the aim of expanding on this and assessing the efficacy of CCE in "real life practice" via short and long term follow up with their study population post CCE.

The patient population included all patients who had a CCE done with the Pillcam Colon 2, from the time span of 2011 to 2016. Multiple patient factors were recorded prior to the study, including patient demographics, indication for CCE, bowel cleansing grade, and completeness of colon exploration. Bowel cleanliness was graded on a scale of 1 through 4, using the Leighton-Rex scale (1 = poor, 2 = fair, 3 = good, 4 = excellent).

Prior to ingestion of the capsule, patients were placed on a 1-day clear liquid diet and bowel preparation with 4 or 2 liters of polyethylene glycol. Two days after capsule ingestion, the patients received an additional dose (30 or 45mLs) of sodium-phosphate solution. The videos captured by CCE were then read by trained gastroenterologists. During the 5 year study, 1,282 CCEs were completed, 689 of which were considered for full CCE report. The patients were evenly split by gender and the average age was 70. The main indications for colon imaging were intestinal symptoms, personal or familial history of colonic neoplasia, and iron deficiency anemia. The main indications for CCE were contraindication to colonoscopy, incomplete colonoscopy, and patient refusal to undergo colonoscopy. 280 of the 689 patients then underwent colonoscopy post CCE for further imaging. The main indications for colonoscopy were significant polyp(s) identified (49.6%) and incomplete or insufficient bowel cleaning (25.4%).

64.2% of the CCEs were considered complete (all colonic segments were seen) and 48.9% of the CCE's were considered complete with excellent or good bowel cleansing. Bowel cleanliness was considered excellent or good in 69.2% of the cases and fair or poor in 27.6%. Polyps were identified on 298 CCEs and 187 of those were deemed significant polyps. 83 of the 187 significant polyps (44.4%) were identified in CCEs described as incomplete or without bowel cleansing.

228 of the overall patients were recommended to do a colonoscopy post CCE. 45.2% of these patients were diagnosed with polyps, 10.3% of which were classified as advanced neoplasia. 4.5% of the original 689 CCEs resulted in the diagnoses of advanced neoplasia. Consistent findings between colonoscopy and CCE were found in 110/228 (48.2%) of the colonoscopy post CCE cases. Consistent findings amongst CCE, colonoscopy, and surgery were found in 26/32 (81.3%) of the cases that fit the criteria for all three procedures. Of the 6/32 other cases, CCE was non-significant, but upon colonoscopy found to have advanced neoplasia, indicating that a critical diagnosis had been missed with solo CCE use. 4 of these cases had fair (1) or poor (3) bowel cleansing.

Some limitations of the study include that colonoscopy was only compared to CCE in the patients who had indications for further imaging. There is no control to compare against for assessment of the viability of the CCE's diagnostic power in patients who had no indications for colonoscopy. Additionally, while each patient was assigned the same bowel regimen, there is no way to know regimen compliance. Even with optimized bowel preparation, more than half of the patients had incomplete preparation. This shows to have an impact on CCE diagnostic power in the study because most of the missed cases of neoplasia were reported in patients with incomplete CCE and CRC not visualized in the distal colon. So while complete CCE can be recommended as a CRC screener in patients with complete preparation, the same recommendation cannot be extended to patients with incomplete bowel preparation.

Other limitations to be considered are patient demographics. The study was conducted in France, where attitudes towards colonoscopy may be different than in the U.S.. One of the leading indications for CCE was patient refusal for colonoscopy. Although this helped in that it provided a larger sample size, it excluded patients that might have stronger indications for colonoscopy. The majority of colonoscopy refusals were in "elderly" and "fragile" patients, resulting in a population that does not represent the population of usual colonoscopy recipients. The average patient age was 70 years old with an interquartile range of 61-79. With



newer guidelines requiring colonoscopy screenings starting at 45 years of age and other indications outside of screening such GI bleed that can occur in younger patients, this excludes a significant age range from the bulk of the study. Additionally, 107 of the original 689 patients were lost to follow-up, resulting in selection bias.

This paper represents level 2 evidence.¹⁰

Clinical Application

The ability of CCE to replace colonoscopy has been largely explored in the research sphere, but limited in its clinical application and implications on patient health outcomes. Benech et al. are innovative in their 5-year study of patient CCE and proceeding colonoscopy outcomes, but the study was ultimately limited in its diagnostic power for patients with incomplete bowel preparation. The study showed that CCE missed 6 cases of advanced neoplasia upon further colonoscopy exploration, 4 of which were in patients with incomplete bowel preparation or incomplete CCE due to incomplete visualization of the whole colon.⁴ While the overall study points in the favor of CCE as a screener followed by colonoscopy in patients with the indication for further exploration, it does not stand alone as a solitary imaging modality in patients with incomplete bowel preparation. With that being said, this dual visualization method is not unpractical and suggests the opportunity for changes in the classical colon screening methods.

Looking at our patient, it is possible to apply the case outcomes to his clinical course. Although our patient does not fit the patient demographics, he does share similar indications for imaging. Similar to 21.5% of the patients, Mr. Hudson required imaging due to iron-deficiency anemia etiology exploration.⁴ 31.5% of the patients' primary indication for CCE was incomplete bowel preparation, putting Mr. Hudson in the same category as almost one third of the participants.⁴ Looking at the qualitative implications, the study could potentially be extended for clinical recommendation in Mr. Hudson's case. This would suggest that a viable option for diagnosis is CCE. However, this plan of action does eliminate the risk of missed diagnosis due to his confounding incomplete bowel preparation, putting him at a higher risk of missed diagnosis on CCE, if not followed by colonoscopy.

Because it is difficult for Mr. Hudson to get to his appointments, it is preferential that he receives inpatient care. The dual CCE and colonoscopy examination would be practical, considering he is already in the hospital, is amenable to testing and treatment recommendations from his health care team, and has insurance that would cover the extra imaging procedures. However, this does not take into account the accessibility or availability of CCE. While CCE technology has significantly expanded since its inception, it is currently only used in limited scenarios, the primary one being diagnosis of irritable bowel disease at our quaternary center. Because of this, the option of CCE followed by colonoscopy testing was not available to our patient, regardless of the risks and benefits to the suggested CCE co-testing.

Although Benech et al. propose an alternative method for colonoscopy imaging that takes into account incomplete bowel preparation, considering the lack of CCE technology availability and risk of missed diagnosis, the conclusion is reached that there is no viable alternative to colonoscopy imaging proposed in the current research literature. CCE followed by colonoscopy is not yet an option in the majority of hospitals. While the sources evaluated in the related literature section propose alternatives to colonoscopy that are accessible to the patient population and do not carry the risk of missed diagnosis, they cannot be extended to patients with incomplete bowel preparation. Based on this information, it is found that there are no accessible alternatives for imaging that is viable for a patient with incomplete bowel preparation. Therefore, the clinical question cannot be answered in relation to this patient scenario.

A pragmatic method for bowel preparation in patients with difficult preparation involves placing a nasogastric tube and continuously flushing it with the bowel preparation fluid until the preparation runs clear from the rectum. At this point, colonoscopy can be complete with full visualization. This method suggests a practical inpatient method for bowel preparation that could be applied to our patient with the correct resources and nursing assistance. A comparative efficacy trail should be considered.¹¹



After Mr. Hudson's incomplete colonoscopy, the options were discussed with the patient and via shared decision making, it was decided that he would have no further imaging or diagnostic procedures done during his stay in the hospital. The care teams concluded that it would be unlikely that he would be able to undergo successful bowel preparation and they could not offer him a CCE due to current hospital limitations. Despite continued efforts and full compliance, Mr. Hudson was unable to successfully complete bowel preparation. Because of this, there were no alternative imaging modalities available to his GI team. Additionally, Mr. Hudson felt that he had been in the hospital for too long and was ready to go home. After his hemoglobin stabilized, Mr. Hudson was restarted on his previous dose of plavix and discharged from the hospital without further efforts to identify the etiology of his bleeding. His instructions were to (1) follow up with neurology to determine if he needed to continue his plavix dose and (2) follow up with his primary care, and (3) attempt to repeat his colonoscopy in 1 year time.

New Knowledge Related to Clinical Decision Science

Studies show that lower socioeconomic status (SES) and Medicaid insurance are correlated with higher rates of incomplete bowel preparation for colonoscopy.^{12,13} Not only is bowel preparation majorly under-researched as a stand alone topic, patients with incomplete bowel preparation have furthermore been repeatedly excluded from studies on methods for colonoscopy alternatives, as seen in the conducted literature review. While alternatives for colonoscopy due to incomplete colonoscopy have been considered, they have not been considered within the context of bowel preparation in a manner that lends itself to clinical application, especially in regards to Mr. Hudson.

This combination of increased relevance in lower SES and underserved populations with the de-emphasis of bowel preparation in research points to a glaring health care gap in an already disenfranchised population. Whether due to comorbidities, physical inability to complete the bowel regimen, or simple issues of non-compliance, incomplete bowel preparation is a clinically significant clinical dilemma due to its implications on colonoscopy completion. Studies show that incomplete colonoscopy rates are as high as 4% to 25% and are associated with higher rates of colon cancer.¹⁴ Considering colonoscopy is the golden standard for CRC detection, viable alternatives are needed to ensure complete detection in the patient population.

As common as colonoscopy has become in standard medical management and CRC screening, this clinical appraisal shines a light on the hidden patient population that are excluded from this. Future research must evaluate for practical, accessible, and clinically relevant alternatives to traditional colonoscopy in patients that do not meet criteria, particularly patients unable to complete bowel preparation.

Conflict Of Interest Statement

The author declares no conflicts of interest.

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