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Comparison of Completion Rate and Diagnostic Yield for Endoscopically Placed *Versus* Swallowed Capsule Endoscopy in Hospitalized Patients

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Abstract

This is a retrospective study comparing completion rate and diagnostic yield of Capsule Endoscopy (CE) when placed endoscopically versus swallowed in hospitalized patients who have undergone same-day upper endoscopy, colonoscopy, or bidirectional endoscopy. We analyzed patient characteristics, completion rate, and diagnostic yield for endoscopically placed and swallowed CE. Over a ten-year period, 101 CE exams were performed in 97 hospitalized adult patients who underwent same-day upper endoscopy, colonoscopy, or bidirectional endoscopy. The capsule was endoscopically placed in 61patients (60.4%) and swallowed in 40 (39.6%). Completion rate was 90.2% for endoscopically placed CE and 77.5% for swallowed (*P*=0.08). Diagnostic yield was 37.7% for endoscopically placed CE and 42.5% for swallowed (*P*=0.63). Factors associated with higher incompletion rate of swallowed CE included gastric transit time ≥120 minutes, moderate sedation, overt GI bleeding, and CE with 8-hour battery life. None of the recorded variables had a significant influence on diagnostic yield. In conclusion, we observed a statistically insignificant trend toward higher completion rate for endoscopically placed CE versus swallowed CE. There was no difference in diagnostic yield between endoscopically placed and swallowed CE.

Keywords: Capsule endoscopy; Completion rate; Diagnostic yield; Hospitalized patients

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Abbreviations

BDE: Bidirectional Endoscopy; BMI: Body Mass Index; CE: Capsule Endoscopy; CR: Completion Rate; DY: Diagnostic Yield; EGD: Esophagogastroduodenoscopy; GA: General Anesthesia; GI: Gastrointestinal; GTT: Gastric Transit Time; IDA: Iron Deficiency Anemia; MAC: Monitored Anesthesia Care; MS: Moderate Sedation; SBTT: Small Bowel Transit Time; SD: Standard Deviation; TTT: Total Transit Time; UE: Upper Endoscopy

Introduction

Capsule Endoscopy (CE) is a useful tool for evaluation of suspected small bowel pathology [1]. It is commonly performed in hospitalized patients, generally for suspected small bowel bleeding. Completion of CE to the cecum during the capsule's battery life is an important factor in optimizing diagnostic yield. Incomplete exams occur in 16-20% of patients undergoing CE, often due to slow gastrointestinal transit [2,3]. This may result in missed pathology, particularly in the distal small bowel [4]. Hospitalized patients are at particularly increased risk for incomplete CE due to slow GI motility for a number of reasons: critical illness, physical immobility, presence of a comorbid disease affecting motility, and receiving medications that slow motility (i.e., opioids and anti-cholinergics) [4-6]. Specifically, hospitalized patients seem to have longer gastric transit times than outpatients [7]. Certain anesthetic agents used during surgery have also been suspected to decrease GI motility, though evidence on this in the realm of endoscopy is scarce [8].

Several methods have been suggested to increase CE Completion Rate (CR) and Diagnostic Yield (DY), including the use of prokinetics, bowel preparation, and endoscopic placement of the capsule [9-11]. Endoscopic deployment directly into the small bowel should theoretically improve CR by removing the risk of gastric retention, but existing data on CR and DY is conflicting [12-14] and has not been evaluated specifically for inpatients who have undergone same day standard endoscopy. Our study aims to compare CR and DY of endoscopically placed versus swallowed CE in hospitalized patients who have undergone same-day Upper Endoscopy (UE), colonoscopy, or

Bidirectional Endoscopy (BDE).

Materials and Methods

This retrospective study received approval from our Institutional Review Board. We performed a search of our institution's clinical data warehouse with a date range from January 1, 2010 through February17, 2020 for patients who met the following criteria: CE with a same-day EGD or enteroscopy, colonoscopy, or both (bidirectional endoscopy) at our academic medical center; age ≥18 years; and in-patient status when endoscopies were performed. Patients were excluded if on chart review they did not meet all of the aforementioned inclusion criteria. Data extracted from charts included: patient age; Body Mass Index (BMI); method of anesthesia used during standard endoscopy; indication for CE; presence of anemia at time of CE; method of capsule ingestion (i.e., endoscopically placed or swallowed); Gastric Transit Time (GTT), in minutes; Small Bowel Transit Time (SBTT), in minutes; Total Transit Time (TTT), in minutes; completion of CE (Yes/No); and presence of and description of clinically significant CE findings, where applicable.

GTT was defined as time from ingestion of capsule until the first small bowel image. GTT was not recorded if CE was endoscopically placed directly into small bowel. SBTT was defined as time from the first small bowel image to the first image of the cecum. A CE exam that did not reach the cecum was considered incomplete. Exams that were incomplete due to capsule battery expiration in the stomach or in small bowel did not have those respective transit times recorded-i.e., GTT was not reported if the capsule did not reach the small bowel from the stomach and SBTT was not reported if the capsule did not reach the cecum. TTT was taken as the sum of GTT, where applicable, and SBTT. GTT was reported for both complete and incomplete exams, as long as the capsule exited the stomach. SBTT and TTT were only reported for complete CE exams. Diagnostic yield for CE was defined as a clinically significant CE finding in the small bowel that was explanatory of the patient's presenting complaint.

Patients did not receive a standardized bowel preparation specifically in regard to CE. Rather, patients were prepped according to the type of standard endoscopy performed. Those who underwent colonoscopy or bidirectional endoscopy were prepped with a standard PEG solution of 2-4 liters starting the evening before the procedure. Those who had only upper endoscopy were simply kept nothing by mouth after midnight prior to the procedure. CE exams were performed using either PillCam SB, PillCam SB2, or PillCam SB3 CE (Given Imaging, Yoqneam, Israel; Medtronic, Minneapolis, MN). For endoscopically placed capsules, an Advance capsule endoscope delivery device (Steris plc., Dublin, Ireland) or Roth Net (Steris plc., Dublin, Ireland) was used to deliver the capsule. Patients with endoscopically placed CE were allowed liquids 30 minutes after capsule placement and food 2 hours after capsule placement. Patients who swallowed CE were allowed liquids 2 hours after capsule ingestion and food 4 hours after capsule ingestion. Patients wore a recorder belt that uploaded images to RAPID™ Reader Software or PillCam™ Software (Medtronic, Minneapolis, MN)and studies were reviewed and interpreted by one of three endoscopists with extensive experience in CE (including author AB).

Clinical data was entered into Microsoft Excel 2016 (Microsoft Inc., Redmond, WA) and statistical analysis was performed using SPSS Statistics version 25.0 (IBM Corp, Armonk, NY). Tests of statistical significance for categorical variables were done using Pearson's Chi-squared or Fisher's exact tests as appropriate. Additionally, two-tailed T-tests were performed where appropriate. Statistical significance was defined as *P*-value<0.05.

Table 1: Patient, endoscopy, anesthesia, and capsule endoscopy characteristics separated according to whether CE was endoscopically placed or swallowed. Count and percentages for all recorded variables for each group with test of significance.Pearson's Chi-square test was used for test of significance.

	Endoscopically Placed (*n* = 61)	Swallowed (*n* = 40)	*P*-value
Completion Rate (CR)	55/61 (90.2%)	31/40 (77.5%)	0.08
Diagnostic Yield (DY)	23/61 (37.7%)	17/40 (42.5%)	0.63
Age in years (mean +/- SD)	61.9 +/- 16.1	65.1 +/- 12.6	0.29
BMI in kg/m^2(mean +/- SD)	28.2 +/- 7.1	29.6 +/- 4.7	0.30
Female	29/61 (47.5%)	19/40 (47.5%)	0.99
Indication for CE	-	-	0.52
Overt GI Bleed	43/61 (70.5%)	27/40 (67.5%)	-
Melena	27/61 (44.3%)	19/40 (47.5%)	-
Hematochezia	16/61 (26.2%)	7/40 (17.5%)	-
Hematemesis	-	1/40 (2.5%)	-
IDA/Occult GI Bleed	17/61 (27.9%)	13/50 (32.5%)	-
Crohn's	1/61 (1.6%)	-	-
Anemic at time of CE	60/61 (98.4%)	40/40 (100%)	0.42
CE retained in stomach	-	3/40 (7.5%)	-
Prior incomplete SCE	7/61 (11.5%)	-	-
Follow up ECE that reached cecum	6/7 (85.7%)	-	-
Type of Same-day Endoscopy	-	-	< 0.001
Upper endoscopy only (UE)	30/61 (49.2%)	5/40 (12.5%)	-
Colonoscopy only	-	15/40 (37.5%)	-
Bidirectional endoscopy (BDE)	31/61 (50.8%)	20/40 (50%)	-
Type of Anesthesia	-	-	0.05
Monitored anesthesia care (MAC)	30/61 (49.2%)	23/40 (57.5%)	-
General anesthesia (GA)	20/61 (32.8%)	5/40 (12.5%)	-
Moderate sedation (MS)	11/61 (18%)	12/40 (30%)	-

CR=Completion Rate; DY=Diagnostic Yield; CE=Capsule Endoscopy; ECE=Endoscopically placed Capsule Endoscopy; SCE=Swallowed Capsule Endoscopy; UE=Upper Endoscopy; BDE=Bidirectional Endoscopy; IDA=Iron Deficiency Anemia

Results

Patient characteristics

Our initial search yielded 104 in patients who underwent CE with same-day UE, colonoscopy, or BDE. Seven patients were excluded when chart review revealed they did not meet all inclusion criteria. 101 CE's were reviewed in the remaining 97 patients who met inclusion criteria. Forty-six of the 97 patients (48 of the 101 CE cases) were female. Four patients had 2 CE exams. Mean patient age was 63.1+/-14.8 years (range 22-93 years). Mean BMI was 28.7+/-6.3 kg/m^2. For a summary of all patient characteristics, see Table 1.

Endoscopy characteristics

In regard to same day endoscopy, 31/101 (30.7%) had solely upper endoscopy, 15/101 (14.8%) had solely colonoscopy (all in the swallowed CE group), and 51/101 (50.5%) had both UE and

Table 2: Completion rate and diagnostic yield for endoscopically placed versus swallowed CE separated according to individual variables. For test of significance, Pearson's Chi-square or Fisher's exact test was performed as appropriate.

	Completion Rate (CR)			Diagnostic Yield (DY)		
	Endoscopic	Swallowed	*P*-value	Endoscopic	Swallowed	*P*-value
All Patients	55/61 (90.2%)	31/40 (77.5%)	0.08	23/61 (37.7%)	17/40 (42.5%)	0.63
Indication for CE						
Overt GI Bleed	40/43 (93%)	20/27 (74.1%)	0.03	16/43 (47.2%)	10/27 (37%)	0.99
Melena	26/27 (96.3%)	13/19 (68.4%)	0.01	11/27 (40.7%)	8/19 (42.1%)	0.93
Hematochezia	14/16 (87.5%)	6/7 (85.7%)	0.91	5/16 (31.3%)	2/7 (28.6%)	0.9
Hematemesis	-	1/1 (100%)	-	-	0/1 (0%)	-
IDA/Occult GI Bleed	14/17 (82.4%)	11/13 (84.6%)	0.87	6/17 (35.3%)	7/13 (53.8%)	0.31
Crohn's Disease	1/1 (100%)	-	-	1/1 (100%)	-	-
Capsule Battery Life						
8-hour	25/26 (96.2%)	17/24 (70.8%)	0.02	8/26 (30.8%)	12/24 (50%)	0.17
12-hour	30/35 (85.7%)	14/16 (87.5%)	0.86	15/35 (42.9%)	5/16 (31.3%)	0.43
Anesthesia Used						
MAC	28/30 (93.3%)	20/23 (87%)	0.43	12/30 (40%)	10/23 (43.5%)	0.8
GA	16/20 (80%)	4/5 (80%)	1	9/20 (45%)	2/5 (40%)	1
Moderate Sedation	11/11 (100%)	7/12 (58.3%)	0.04	2/11 (18.2%)	5/12 (41.7%)	0.22
Type of Endoscopy						
UE only	26/30 (86.7%)	4/5 (80%)	0.69	10/30 (33.3%)	2/5 (40%)	1
Colonoscopy only	-	12/15 (80%)	-	-	6/15 (40%)	0.44
BDE	29/31 (93.5%)	15/20 (75%)	0.06	13/31 (41.9%)	9/20 (45%)	0.83

CE=Capsule Endoscopy; IDA=Iron Deficiency Anemia; MAC=Monitored Anesthesia Care; GA=General Anesthesia; UE=Upper Endoscopy; BDE=Bidirectional Endoscopy

colonoscopy (see Table 1 for full results separated by method of CE placement). The type of same-day endoscopy performed differed significantly between the endoscopically placed and swallowed groups ($P<0.001$); see Table 1 for full details. By our definitions, all patients with endoscopically placed CE were classified as having undergone UE or BDE. Of the 31 patients with endoscopically placed CE who had BDE, EGD was performed for the sole purpose of CE placement in 4 cases. The two aforementioned statements likely account for the significant difference observed in type of endoscopy performed between the endoscopically placed and swallowed CE groups. In regard to type of anesthesia used during standard endoscopy, 53/101 (52.5%) received monitored anesthesia care with Propofol (MAC), 25/101(24.8%) received general anesthesia (GA), and 23/101 (22.8%) received Moderate Sedation (MS) with a combination of a benzodiazepine and an opioid. For patients that received moderate sedation, CR was significantly higher in the endoscopically placed group *vs* swallowed (100% *vs* 58.3%, $P=0.037$). See Table 2 for other comparisons of CR and DY between the endoscopically placed and swallowed CE groups according to different variables.

Capsule endoscopy characteristics

In 60.4% of cases (61/101), CE was endoscopically placed and in the remaining 39.6% (40/101) CE was swallowed. Completion rate was 90.2% for endoscopically placed capsules and 77.5% for swallowed ($P=0.08$). Diagnostic yield was 37.7% for endoscopically placed capsules and 42.5% for swallowed ($P=0.63$). All but one case in our sample had suspected small bowel bleeding as the indication for CE: 70/101 (69.3%) for overt GI bleeding including melena (46/101), hematochezia (23/101), and hematemesis (1/101); 30/101 (29.7%) for iron deficiency anemia and occult GI bleed; one patient in our series had CE for surveillance of known Crohn's disease. For comparison of CR and DY according to all recorded variables for both swallowed and endoscopically placed CE, see Table 2. We observed no significant difference in CR or DY for 8-hour versus 12-hour capsules overall; however, when separated by method of placement, an 8-hour capsule was significantly more likely to reach the cecum if placed endoscopically compared to swallowed (CR 96.2% *vs* 70.8%, $P=0.015$). CE exams with GTT ≥120 minutes had a significantly lower CR (4/8 or 50%) when compared to those with GTT<120 minutes (26/28 or 92.9%) (Fisher's exact test, $P=0.014$); this does not include the three CE exams that were retained in the stomach. Twenty-seven of the 28 cases with GTT recorded had swallowed CE. See Table 3 for comparison of transit times for endoscopically placed versus swallowed CE.

Table 3: Comparison of transit times between endoscopically placed and swallowed capsule endoscopy. Two-tailed t-test was performed.

	Endoscopic		Swallowed	
	Median +/- SD	*n*	Median +/- SD	*n*
GTT (min.)	346	1	41 +/- 156	35
SBTT (min.)	292.5 +/- 163.2	52	259 +/- 156.1	30
TTT (min.)	292.5 +/- 170.3	52	297 +/- 175.6	30

GTT=Gastric Transit Time; SBTT=Small Bowel Transit Time; TTT=Total Transit Time; SD=Standard Deviation

Discussion

We observed a non-significant trend toward a higher CR with endoscopic placement of CE versus swallowed. Though statistical significance was not reached, the observed difference in CR may be of clinical significance. Incomplete CE can result in the need

for additional studies or procedures, thus adding risk and cost to the patient. For example, seven patients in our study had a history of an incomplete swallowed CE exam. When CE was repeated with endoscopic placement in those patients, 6 out of 7 resulted in a complete CE. Furthermore, endoscopic placement at the time of standard endoscopy adds minimal time and risk. Despite the difference in CR, we did not observe a difference in the DY of CE between the endoscopically placed and swallowed CE groups. Additionally, none of the variables that we assessed had a significant effect on DY comparing endoscopically placed and swallowed CE. Even variables with a significant difference in CR did not have an effect on DY.

We found several characteristics to be associated with a lower CR in the swallowed group compared to endoscopic placement: GTT≥120 minutes, 8-hour capsule battery life, use of moderate sedation anesthesia, and overt GI bleeding as the indication for CE. Of the 9 incomplete CE exams in the swallowed group, 4 had a GTT of ≥120 minutes and 3 were retained in the stomach for the entirety of the capsule's battery life. Thus, delayed gastric emptying, rather than impaired small bowel transit, seems to be the major factor leading to incomplete exams for patients who swallowed the capsule; this is easily overcome by placing the capsule endoscopically into the small bowel. As previously mentioned, hospitalized patients have many reasons for impaired gastric emptying. Prior studies have echoed these findings, reporting increased GTT in hospitalized patients compared to outpatients, but no difference in SBTT [5, 7].

Despite improvements in battery life with newer generation capsules, we observed no overall difference in completion rates between 8-hour and 12-hour capsules, except when comparing endoscopically placed *vs* swallowed 8-hour devices. Additionally, we observed no difference in diagnostic yield between 8-hour and 12-hour capsules overall nor when separated by method of placement. In a study by Rahman et al., 12-hour capsules had a higher completion rate than 8-hour capsules (88% *vs*. 79.5%, *P*=0.03) [15]. A similar study by Ou et al., also noted a trend toward higher completion rate in 12-hour capsules, though it did not reach statistical significance [16]. Neither of these studies found 12-hour capsules to have a higher diagnostic yield. Interestingly, Rahman et al., observed a higher diagnostic yield with the 8-hour capsules [15]. In summary, the results in the literature are mixed.

The effect of moderate sedation on swallowed CE CR may in part be due to opioids' effects on gastrointestinal motility *via* the peripheral nervous system, especially in regard to gastric emptying [17]. In all three cases where CE was retained in the stomach, moderate sedation anesthesia had been used. At our institution, Monitored Anesthesia Care (MAC) with Propofol has virtually replaced moderate sedation for hospitalized patients undergoing standard endoscopy. In a prospective study of outpatients undergoing same-day colonoscopy and capsule endoscopy, Propofol (compared to no sedation) had no effect on CR but did prolong SBTT; GTT was not recorded [18]. We could not find any studies directly comparing the use of MAC versus moderate sedation during endoscopy with respect to effects on GI motility.

Other methods proposed for improving CR include use of promotility agents such as metoclopramide or erythromycin, use of a standardized PEG preparation with or without simethicone, and screening patients prior to CE with patency capsule or CT enterography [9,10,19]. Though again, the data on these techniques are conflicting [20]. Some groups have also proposed use of a real-time capsule viewer for the first 1-2 hours after a patient swallows the capsule; if the capsule has not entered the small bowel by the 1-2 hour mark, the capsule is endoscopically advanced beyond the pylorus. Gao et al., found this method to improve the rate of complete small-bowel CE examinations and increased diagnostic yield [12]. One of the newest innovations aimed at increasing CR is a magnetically controlled capsule that uses a mobile C-arm to propel the capsule through the pylorus either by remote control or automatically using a pre-programmed mode. One group found that this tactic significantly shortened GTT and increased CR, but again, DY was not significantly different [21].

The retrospective nature of our study created several limitations. One potential issue is that patients suspected of being high risk for incomplete swallowed CE exam or altogether unable to swallow the CE may have been empirically selected for endoscopic placement, thereby creating a selection bias. A prospective, randomized study would be ideal to control for clinician bias in method of capsule placement. Sample size was another limiting factor. Our study was underpowered for the degree of difference in observed completion rates between swallowed CE and endoscopically placed CE. Additionally, we chose to include repeated measures in order to maintain sample size. This study's location at a tertiary academic center may have resulted in referral bias, so these results are best applied to other large referral centers as opposed to smaller community hospitals. Lastly, as previously stated, not all patients received a standardized bowel preparation.

Conclusion

Endoscopic placement of capsule endoscopy may result in a higher completion rate compared to oral ingestion in hospitalized patients; however, the observed difference in this study did not reach statistical significance. Additionally, the higher CR in the endoscopically placed group did not translate to higher DY. Regardless, the clinical implications may be significant in that higher completion rates can result in the avoidance of repeat endoscopy for capsule placement as well as decreasing the need for additional studies to reach a diagnosis.

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