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Capsule Endoscopy in Left Ventricular Assist Device Patients: Retrospective Review of Efficacy and Necessity

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Abstract

Background

Capsule endoscopy (CE) is mainstream in the evaluation of obscure gastrointestinal bleeding (GIB) in the general population. However, the diagnostic and therapeutic impact of CE in LVAD patients susceptible to transient bleeding remains largely unexplored. This study aimed to assess the benefits of CE in the evaluation of LVAD associated GIB.

Methods

Retrospective review of patients implanted with a continuous flow LVAD who underwent inpatient capsule endoscopy (CE) between January 2014 and May 2017 at our center. Identification of lesions with high bleeding potential or presence of frank blood were considered abnormal findings on CE study.

Results

Twenty-five inpatients who underwent 41 CE were identified. All patients presented with GIB and had preceding negative upper endoscopy and colonoscopy in the past 4 weeks. On the first capsule in each patient, 19 had interpretable images, abnormal findings were detected in 5 patients (high risk lesion in 3, frank blood in 2), four of these underwent an enteroscopy and only 2

(8%) patients had confirmation of the capsule findings with APC treatment (true positive). Excluding patients with malfunction, LVAD interference and poor bowel prep, 14 patients had negative/equivocal CE, of which 4 underwent enteroscopy due to continued bleeding and 2 of these patients had treatable culprit lesions (false negative). A total of 17 (68%) patients were discharged without any therapeutic intervention irrespective of the success or findings on CE due to clinical stabilization. Twenty patients (80%) had recurrence in a mean 154 days.

As expected, repeat capsules in the same admission increased the diagnostic yield (p=0.031)

Only nine patients (36%) had capsule-image evidence of reaching the cecum while 4 patients (16%) had retention which had to be retrieved without further complication.

Conclusions

This study demonstrated that evaluation of GIB with CE is feasible and safe but was associated with a low diagnostic yield and low conversion to therapeutic intervention. With a true positive yield of 4% in our cohort, the efficacy and cost-effectiveness of CE in the LVAD population is debatable. The role of CE in LVAD patients may need to be reevaluated.

An identification of patients who would benefit from a capsule-first approach would allow optimum utilization of resources and reduce healthcare expenditure.

Keywords: Gastrointestinal bleeding, capsule endoscopy, left ventricular assist device, advanced heart failure management

Introduction

Left ventricular assist devices (LVAD) are becoming a progressively more reliable and safe long term treatment option for advanced heart failure patients. As the cohort of LVAD patients continues to grow, various complications that are characteristic of this patient population are becoming evident. Gastrointestinal bleeding (GIB) has been reported in up to 20% patients and contributes to significant morbidity including multiple hospitalizations, prolonged in patient stay, and possibly increased mortality [1,2]. While the number of LVAD patients continues to grow, the ideal approach to further evaluation of GIB without an identified source on standard evaluation with endoscopy and colonoscopy is unknown. Based on guidelines, capsule endoscopy (CE) has been adopted as the procedure of choice in general population for evaluation of gastrointestinal bleeding (GIB) undiagnosed through upper endoscopy/colonoscopy, especially that estimated to originate from the small intestine. While these guidelines have been extrapolated to patients with left ventricular assist device (LVAD), the true efficacy and therapeutic impact of CE in LVAD patients who are prone to transient but recurrent bleeding remains largely unexplored. As the diagnostic and treatment strategies evolve, it is important to understand management options for GIB as well as their associated limitations. This study aims to assess the necessity of this comparatively expensive test through understanding the clinical course of patients

after capsule study and identify its role in screening patients for subsequent enteroscopy, therapeutic intervention or recurrence prevention.

Methods

Study population:

We performed a retrospective review of patients implanted with a continuous flow left ventricular assist device (LVAD) who underwent inpatient capsule endoscopy (CE) between January 2014 and May 2017 at our facility- Jewish Hospital, Louisville, Kentucky. Appropriate Institutional Review Board exemption was obtained.

Patients were given either one gallon of GoLytely prep split between the night prior and morning of the capsule endoscopy study or magnesium citrate prep split with two 300 mL bottles night prior to and one 300mL bottle the morning of the capsule endoscopy. Both preps included two tablets of simethicone 80mg the morning of the capsule endoscopy study.

The PillCam SB2 capsule (Given Imaging, Duluth, GA, United States) was activated and either swallowed by the patient, or in cases of significant dysphagia or delayed gastric emptying, was placed through an upper endoscope directly into the duodenum.

The capsules images were interpreted by certified gastroenterologists. Lesions identified on video capsule endoscopy were classified using the P0-P2 system as described previously by Saurin, J.C. et al. in 2003 [3]. Lesions with no bleeding potential included P0 lesion such as visible submucosal vasculature, non-specific nodules and P1 lesions such as erythema, petechiae or insignificant erosions. Lesions with bleeding potential included P2 lesions such as angiodysplasia, ulcers, significant erosions or adherent clot. Only studies with P2 lesions or the presence of frank bleeding without visualized lesions were considered positive.

Subsequent single balloon enteroscopy findings and treatments offered were noted, confirmation of capsule findings, and treatment with argon plasma coagulation (APC) or endoclips were considered ‘true positive’ findings. The available data until June 2017 was reviewed on all the patients including recurrence and mortality

Statistical analysis:

IBM SPSS (version 19.0, SPSS Corp, Chicago, IL, USA) was used for statistical analysis. Qualitative data is presented as frequencies and quantitative data as mean ± standard deviation.

Results

From January 2014 to May 2017, 25 patients had 41 CEs performed. Of the 41 studies, 28 capsules were performed in the same admission, while others had repeat capsules at 10 days to 7 months for recurrent GIB. Key patient demographics are shown in Table 1. LVAD type was Heart Ware in 9 patients (36%), HeartMate II in 14 (56%) and HeartMate III in 2 patients (8%). Presenting symptoms included melena in 16 patients (64%), hematochezia in 3 (12%), occult

bleeding in 6 (24%). Twenty one patients (84%) were on aspirin at presentation (six patients on 81mg, 15 on 325mg). All patients were on warfarin with a mean INR of 2.54 ± 0.8 on the day of admission.

Table 1: Key demographics

	Frequency (%)
Male gender	19 (76%)
Hypertension	22 (88%)
Diabetes	14 (56%)
Ischemic cardiomyopathy	17 (68%)
Destination LVAD therapy	18 (72%)
ICD	23 (92%)
Ongoing infection	8 (32%)
Previous GIB	19 (76%)
ACEinh/ARB use	9 (36%)
Betablocker	18 (72%)
Statin	13 (52%)
PPI	23 (92%)

Capsule was performed 395 ± 467 days after implantation. The capsule admissions comprised a 10.7 ± 12.4 days inpatient length of stay and the capsule was performed 3.7 ± 2.1 days after admission. All 25 patients had a preceding negative upper endoscopy and colonoscopy in the past 4 weeks and 18 patients (72%) had them on the same hospital admission. Mean transit time for the capsule was 7.28 ± 1.6 hours. Nine patients (36%) had capsule-image evidence of reaching the cecum while 4 patients (16%) had capsule retention which had to be retrieved using upper endoscopy (which occurred without further complication).

While assessing the first capsule endoscopy of each patient, 19 out of 25 patients completed their first capsule with interpretable images. Of the remaining 6 patients, 2 patients had technical malfunction, 2 had LVAD interference with large gaps in image acquisition, one had gastric retention, while one had poor bowel prep. The findings are summarized in figure 1. Of the interpretable 19 CE, capsule identified the following lesions: P0 lesion in 2 (8%), P1 lesion in 4 (16%) and P2 lesion in 3 (12%) while blood was seen without any mucosal lesion in 2 (8%) patients. Of the patients with P2 lesion or identified blood, 4 underwent an enteroscopy and only 2 (8%) patients had findings requiring APC treatment, of which only 1 (4%) had actual visualization of the capsule lesion and treatment (true positive) (Table2). Out of the 14 patients with negative/equivocal CE, 4

underwent endoscopy due to continued bleeding and 2 of these patients had treatable culprit lesions (false negative) (Table 3).

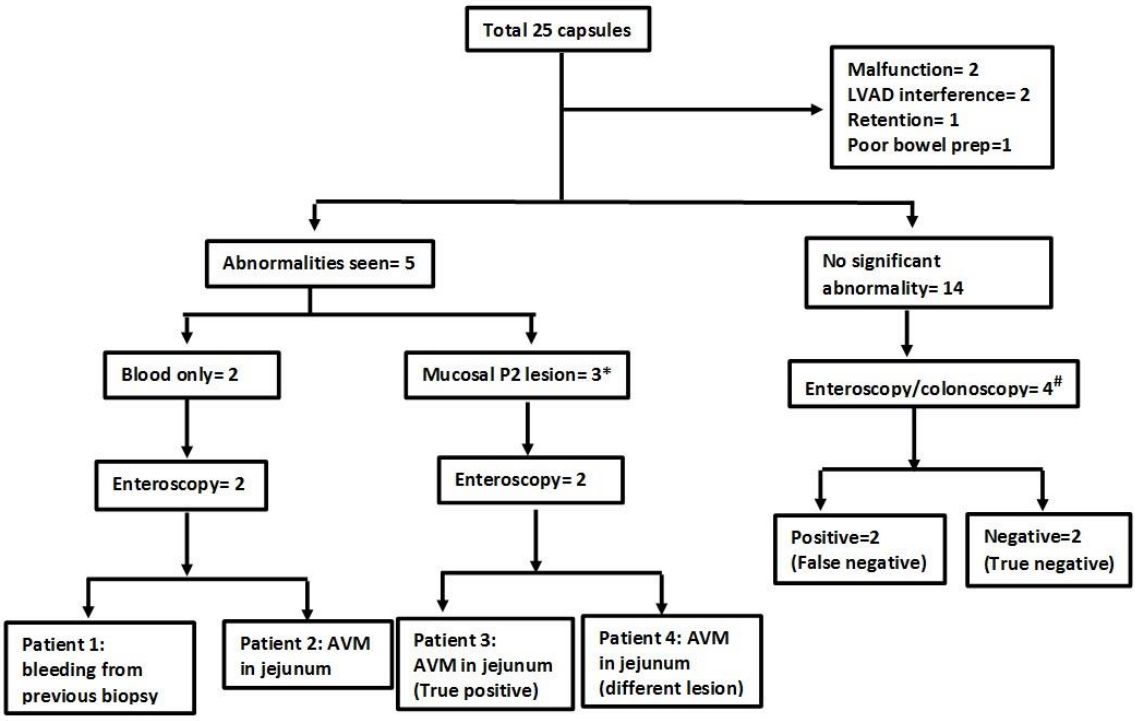

Figure 1: findings of capsule studies

*Mucosal P2 lesions included patients 3, 4 and 5 in table 2
Findings described in table 3

Table 2. Capsules demonstrating abnormal findings

Patient Number	Capsule lesion	Enteroscopy finding	Treatment offered
1	Only blood	Oozing from a previous biopsy site	None
2	Only blood	AVM in jejunum	APC
3	Angioectesia in proximal small bowel	AVM in jejunum	APC
4	Adherent clot in duodenum	AVM in jejunum, no lesion in duodenum	APC
5	Erythematous lesion versus ulceration in the gastric body	Not done	None

Table 3. Endoscopy findings in patients with negative capsules

Patient Number	Capsule lesion	Endoscopy finding	Treatment offered
6	Negative	Bleeding AVM in jejunum	APC
7	Negative	Bleeding AVM in cecum	Endoclip
8	Negative	Negative	None
9	Negative	Negative	None

Thus a total of 8 out of 25 patients (4 with a CE with abnormal findings and 4 with CE with normal finding) underwent enteroscopy post CE, while 17 (68%) patients were discharged without any therapeutic intervention irrespective of the finding on CE because of clinical stabilization Among patients on higher aspirin dose, the dose was reduced or stopped in 6 (33%) at discharge and this was independent of the capsule findings.

Ten patients had >1 CE done, 3 patients had them repeated in the same admission, of these 2 had malfunction of the first capsule while 1 had a negative first study which prompted a repeat due to continued bleeding. Two of these repeated capsules had positive findings. As expected, repeating the capsule in the same admission resulted in better diagnostic yield (p=0.031). The CE which shortly followed the initial negative study showed blood without a mucosal lesion and this prompted an enteroscopy and APC of a jejunal lesion and this patient has not had recurrence since.

Out of the remaining patients with repeat capsules, 2 patients had repeat capsules delivered through upper endoscopy in subsequent admissions while 2 patients had 3 and 4 CE studies each, all of which were negative. The findings are summarized in table 4.

Recurrent GIB was seen in 20 (80%) patients in a mean 154 ± 188 days after the first capsule. Of the 5 patients who had bleeding lesions treated in the initial admission, 4 had recurrent GIB. Two patients died from non-gastrointestinal complications (stroke and intracranial bleeding)

Table 4 Findings of first 2 capsules in patients with repeat capsule endoscopies

Patient number	1st Capsule	2nd Capsule	Subsequent endoscopy findings
1	No Images- LVAD interference	No images- LVAD interference	Endoclips applied to bleeding AVM in ascending colon
2	Technical malfunction	Only blood without mucosal lesion	Oozing from previous biopsy site
3	Technical malfunction	Only blood without mucosal lesion	APC of AVM in jejunum
4	Gastric retention	Negative	Not done
5	Negative	Non-bleeding AVM in proximal small bowel	Not done
6	Negative	Colonic AVM	APC of bleeding AVM in cecum
7	Negative	Negative	Not done
8	Negative	Only blood without mucosal lesion	Not done
9	Negative	Negative	Not done
10	Negative	Negative	Not done

Discussion

The purpose of this study was to evaluate a cohort of LVAD patients undergoing capsule endoscopy (CE) and assess the impact of this test on the diagnosis, treatment and long term outcome of LVAD patients. Here, we present a large and well characterized case series of the use of capsule endoscopies to evaluate LVAD associated GIB. We found that capsule endoscopy is feasible in LVAD patients, but is associated with a high rate of inadequate/incomplete studies. While CE often demonstrate abnormal findings, the clinical utility of the abnormal findings appears limited.

With the advent of continuous flow LVAD, the incidence of GIB may be expected to rise[4], and risk factors for LVAD associated GIB include older age and renal dysfunction[4]. Unlike earlier pulsatile flow LVADs, continuous flow devices require the use of antiplatelet medications and warfarin. While the use of antiplatelet agents and anticoagulation may contribute to GIB among LVAD patients, several

other etiologies for LVAD associated GIB have been identified including acquired von Willebrand syndrome and impaired platelet aggregation[4]. Additionally, it has been proposed that the chronic low pulse pressure caused by continuous flow devices leads to local tissue hypoperfusion and dilation of vascular beds causing angiodysplasia formation [5]. Clinically significant AVMs may occur as early as 2 months after LVAD implantation and can account for 1/3rd or more of the GIB cases[2,6]. Many such patients may have inaccessible locations of the bleeding or oozing from multiple small and transient vascular ectasias within unreachable locations of the small intestine. Finding such vague pathological lesions can then be challenging, requiring multiple diagnostic and therapeutic procedures. Moreover, the treatment of a culprit-looking lesion does not guarantee against recurrence in the future, which come more often from new channels of bleeding. This can be an ongoing issue for some patients resulting in significant frustration, frequent hospitalization, morbidity and sometimes mortality. In such circumstances, CE has been adopted as the procedure of choice in evaluation of GIB when conventional upper and lower endoscopies are unsuccessful in locating the bleeding within their reachable distances. In cases of GIB without a source identified on EGD or colonoscopy, visualization of the entire gastrointestinal tract including the extent of small intestine with CE or enteroscopy has been recommended[7].

After its initial description in 1990s, capsule endoscopy (CE) has become mainstream in the evaluation of GIB over the past 20 years, especially in patients with occult bleed[8,9]. The current guidelines recommend the use of CE as the next step in evaluation of GIB after conventional upper and lower endoscopies fail to ascertain the location of the bleed in the general population[4]. Studies also recommend CE to precede enteroscopy due to its ability to examine the entire small intestine in a non-invasive manner[4] unless in cases of active bleeding. Enteroscopy may then be performed in cases with high suspicion for a small intestinal lesion despite a negative CE[10]. Using an initial CE approach has been argued as a means to filter patients who do not need an enteroscopy and thus may have favorable long term outcomes[11].

As the capsule travels through the small intestine, it transmits images to a data recorder worn by the patient through a radiofrequency channel[9]. There had been concerns about interference with implantable devices utilizing radiofrequency channels such as pacemakers/defibrillators as well as possible electromagnetic interference with novel technologies such as LVAD[9]. However, studies have not shown any such interference[12,13]. While there are only few published reports so far, the use of CE in LVAD patients appears safe[14,15] however the efficacy and cost-effectiveness profile remains largely unexplored.

In a study of CE in 30 LVAD patients[15], 12 patients were found to have lesions with high bleeding potential or frank blood without mucosal lesions on the CE, of which 50% underwent subsequent procedure. However, the findings of these subsequent procedures and hence confirmation of the exact positive findings (true positive) or therapeutic interventions performed were not reported in that study. The remaining 6 patients in that cohort with positive CE had stabilization of that clinical course, so no procedure was pursued. Thus positive finding on CE did not guarantee a subsequent procedure, a finding similar to our study. In that cohort, the recurrent

bleeding rate was 50% among patients with positive CE irrespective of therapeutic interventions performed during the index admission.

There were many differences between the present and the above mentioned study with similar number of CE. In our study while the 4 enteroscopies performed in patients with an abnormal CEs did identify abnormalities, only 1 patient (4%) was a true positive where the CE demonstrated a lesion which was confirmed and treated on follow-up enteroscopy while another patient had a lesion treated on enteroscopy after CE demonstrated only blood. It is unclear whether the treated lesion was the actual source of the visualized blood. The remaining patients with abnormal findings on CE had non-treatable lesion on enteroscopy (patient # 1 in table 2) or had subsequent clinical stabilization, so no therapeutic intervention was offered in that admission despite a seemingly clinically relevant finding (patient #5 in table 2). In fact, out of the 25 patients, 17 patients (68%) were discharged without any therapeutic intervention subsequent to the CE, irrespective of the finding of the capsule.

Irrespective of the CE results and subsequent management, the recurrence rate for subsequent GIB was high (80%) over the course of the study period, with the first recurrence in a mean of 154 ± 188 days after the first capsule. The low diagnostic yield of CE in this study, low conversion rates to therapeutic interventions, high subsequent clinical stabilization rates and the significant recurrence rate thereafter with absence of direct mortality raises the question of whether the CE was necessary in these patients. Performing CE in an inpatient setting may prolong the length of stay and with a true positive yield of 4% in our cohort of patients, the cost-effectiveness of CE may be debatable.

Amornsawadwattana et al[15] in their above mentioned study reported that the capsule did not reach the cecum in only 2 patients and there was no LVAD interference with image acquisition with any of the capsules. In the present study however, imaging evidence of the capsule reaching cecum was available only in 9 patients and capsule retention was noted in 4 patients requiring endoscopic retrieval which occurred without further complications. Moreover, the yield of CE is critically based on the quality of the bowel prep, technical and mechanical success of the capsule, lack of interference and most importantly, the clinical stability of the patient during the conduct of the study. This significantly restricts the clinical utility of the test requiring repeated tests. On the other hand, Sarosiek et al[16] reported early enteroscopy approach in LVAD patients resulted in less diagnostic tests and faster resolution of GIB. However, enteroscopy carries the significant drawback of being invasive, resource-intensive, physician supervised, requires sedation and possibly anesthetist backup, along with pain and inconvenience for the patient[17]. Also in cases of hidden sources of GIB, CE has been reported to have higher detection rates than double balloon enteroscopy in general population[18] but this has not been evaluated among LVAD patients.

While the debate for the ideal diagnostic test in obscure GIB rages on in the literature, it is also important to consider whether the procedure will provide clinically relevant information in a particular patient. Many such patients may simply respond to an outpatient ‘wait and watch’ approach based on the treating physician’s clinical assessment[15] unless there is clinical deterioration or recurrence, in which case a direct enteroscopy approach may be feasible instead.

The inability to treat the visualized lesions is a significant drawback of CE[17], reducing it to a purely diagnostic or screening procedure.

Also, it is unclear if the higher detection rate with CE translates to higher treatment rate in LVAD patients as CE is essentially a diagnostic test which will need a procedure such as enteroscopy to treat the identified lesion. In this study, the conversion of an abnormal CE finding to a therapeutic enteroscopy was only 2 out of 5 (40%), which was not notably different from the conversion of a normal CE to a therapeutic enteroscopy (2 out of 4 patients) in the same hospitalization. Despite treatment of culprit-looking lesion in 5 patients endoscopically, 4 had recurrent GIB. While a past history of previous GIB is a predictor of recurrent bleeding, the majority of recurrence is from the same bleeding site[1]. Identification of such small, transient, recurrent culprit-looking lesions on CE may require no further treatment, however this needs to be further evaluated.

The use of capsule in LVAD patients was a safe procedure in our study, without any extraneous complications, however capsule retention (4 patients) and LVAD interference with image acquisition (2 patients) was reported in some patients. It was suggested that the data recorder be placed far from the LVAD to reduce the electromagnetic interference[9]. ICDs are also commonly found in this patient population which can also be a rare source of interference with image acquisition[19]. While these issues do not contraindicate the use of capsules in LVAD patients, they do suggest judicious use for the highest clinical benefit.

The limitations of the study included the retrospective design and single facility patient selection. The decision to perform CE or subsequent workup based on the results of the CE were at the discretion of the GI service. The study was underpowered for statistical analysis of patients with positive capsules or for subset analysis of APC treated patients. The site of GIB recurrence was not evaluated, unless the patient underwent capsule study again.

In summary, this study demonstrates low clinical utility of performing CE in LVAD patients with GIB without an identified source on EGD and colonoscopy. It also highlights the need to closely understand the pathophysiology of GIB in LVAD patient and reassess the extrapolation of the diagnostic algorithm involving routine CE use from the general population to the LVAD patients. Instead of offering CE to all occult GIB cases, identification of the patients who would benefit most from a capsule-first approach is necessary for optimum utilization of resources, reduction of healthcare expenditure and improvement of quality-adjusted life years through expedited discharge.

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