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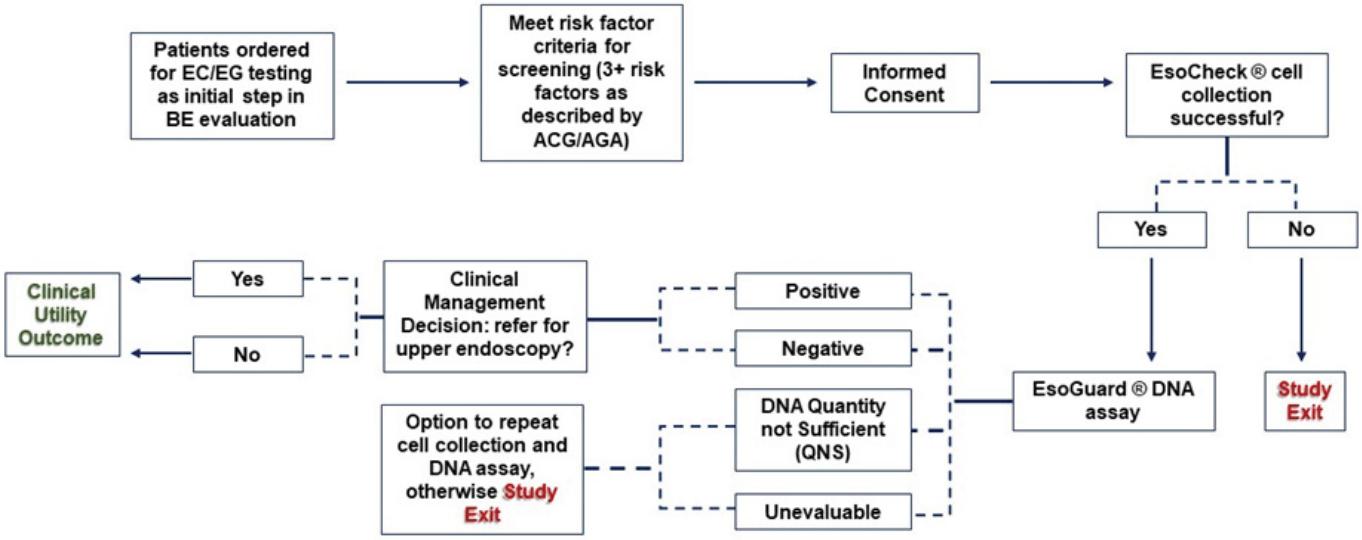

Figure 2: Study Schematic of CLUE (CLinical Utility Study of EsoGuard® on Samples Collected with EsoCheck® as a Triage Test for Endoscopy to Identify Barrett's Esophagus)

Table 1: Subject Baseline Characteristics and BE/EAC Risk Factors

Characteristics	Overall (N = 275)
Age (Yrs)	
Mean ± SD	**61.9±12.6 (271)**
Median (Q1, Q3)	64.0 (55.0,70.0)
(Min, Max)	(23.0,90.0)
Sex	
Female	46.1% (125/271)
Male	**53.9% (146/271)**
Race	
Caucasian Non-Hispanic	**76.0% (206/271)**
Caucasian – Hispanic	4.1% (11/271)
Black or African American	18.5% (50/271)
American Indian or Alaskan Native	0.7% (2/271)
Asian, Native Hawaiian or Other Pacific Islander	1.1% (3/271)
Height (in)	
Mean ± SD	67.6±4.0 (271)
Median (Q1, Q3)	68.0 (65.0,71.0)
(Min, Max)	(59.0,77.0)
Weight (lbs)	
Mean ± SD	205.8±46.2 (271)
Median (Q1, Q3)	201.0 (176.0,230.0)
(Min, Max)	(104.0,390.0)
Calculated BMI (kg/m^2)	
Mean ± SD	31.6±6.3 (271)
Median (Q1, Q3)	31.0 (26.8,35.2)
(Min, Max)	(17.3,53.7)
Obese (calculated BMI ≥30 kg/m^2)	**56.8% (154/271)**
Smoking History	
Current	**18.3% (48/263)**
Former	**34.6% (91/263)**
Never-Smoker	47.1% (124/263)
Family history of BE or EAC	**2.6% (7/270)**
Chronic Gastroesophageal reflux disease (GERD)	**89.7% (243/271)**
Number of years of Gastroesophageal reflux disease (GERD)	
Mean ± SD	14.1±11.6 (228)
Median (Q1, Q3)	10.0 (5.0,20.0)
(Min, Max)	(0.1,72.0)
Is the subject taking, or has the subject taken acid-suppressing medications for management of GERD (e.g., H2 blockers, PPIs, etc.?)	
No	18.5% (50/270)
Yes	81.5% (220/270)
Are/were GERD symptoms controlled with the acid suppressing medications?	
No	18.4% (40/217)
Yes	81.6% (177/217)
3 or more established BE/EAC risk factors (***missing in components are assumed = NO***)	81.8%§ (225/275)
GERD + 3 or more additional risk factors (i.e., cohort meeting **ACG criteria** for BE screening)	73.8% (200/271)

Established BE/EAC risk factors are presented in bolded text
§This deviation from 100% (despite study inclusion criteria) is due to missing components/incomplete data entry being treated as NO for calculation of risk factors

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Table 2: EsoCheck Cell Collection Characteristics

Characteristics	Overall (N = 272)
Was the EsoCheck cell collection successfully completed?	
No	3.7% (10/272)
Yes	96.3% (262/272)
Cell Collection Duration (min)§	
Mean ± SD	6.9±5.9 (267)
Median (Q1, Q3)	4.0 (2.0,12.0)
(Min, Max)	(1.0, 30.0)
Length of sampled esophagus (cm)	
Mean ± SD	6.0±1.2 (249)
Median (Q1, Q3)	6.0 (5.0,7.0)
(Min, Max)	(0.0,10.0)
Were sips of water taken during swallowing of balloon capsule?	
Yes	100.0% (266/266)
Approximate volume of water consumed during the cell collection	
<100mL	96.2% (256/266)
>100mL	3.8% (10/266)
Was the lower esophageal sphincter (LES) able to be felt during the first or subsequent cell collection attempts?	
No	5.6% (3/54)
Yes	94.4% (51/54)

*For subjects who required more than one collection attempt, only the latest-most attempt was included in the count
§Rounded to the nearest minute when documented in the data capture system

EsoCheck Cell Collection

EC cell collection was performed in accordance with the device's instructions for use (IFU, available upon request from https://www.luciddx.com/esocheck). EC cell collection information was documented for 272 subjects, among which 96.3% successfully completed the process (Table 2). Subjects unable to tolerate cell collection (3.7%, 10/272) were exited from the study early. Median cell collection time was 4 min; 119/267 subjects (44.5%) completed the cell collection in 3min or less and the fastest cell collections occurred in under one minute (rounded up to the nearest minute). A maximum collection time of 30min was seen in one individual who required several attempts to swallow the EC device. All subjects utilized small sips of water to facilitate device swallowing, and mean length of sampled esophagus was 6cm, both of which are appropriate per the device IFU.

Table 3A: Summary of EsoGuard Results and Physician Decisions on Endoscopy Referral

Characteristics	Overall (N = 272*)
Was the EsoGuard assay completed on the collected cell sample?	
No**	4.1% (10/242)
Yes	95.9% (232/242)
EsoGuard assay result:	
NEGATIVE	65.5% (152/232)
POSITIVE	29.3% (68/232)
QUANTITY NOT SUFFICIENT (QNS)	3.4% (8/232)
UNEVALUABLE	1.7% (4/232)
Was the subject referred for upper endoscopy?	
No	69.4% (159/229)
Yes	30.6% (70/229)
Provide the reason for referring or not referring the patient for an endoscopy:	
Due to NEGATIVE EsoGuard Result	65.9% (151/229)
Due to POSITIVE EsoGuard Result	29.7% (68/229)
OTHER	4.4% (10/229)
Other, please specify:	
Endoscopy required for evaluation of reflux surgery§	10.0% (1/10)
Patient refused endoscopy⸸	10.0% (1/10)
QNS or unevaluable EsoGuard result – pending repeat test; no endoscopy referral until further results available	50.0% (5/10)
Unevaluable EsoGuard result – subject referred for endoscopy rather than repeat test, given his/her risk factors	10.0% (1/10)
QNS EsoGuard result – subject not warranted for endoscopy without a positive result	20.0% (2/10)

*All subjects who completed EsoCheck cell collection are included in this count, even if EsoGuard results have not yet been processed; average time from cell collection to results is 7-14 days; some results may also have been received by the ordering provider but not yet entered in the study database

**Cell samples shipped to the Central Lab for analysis but for which EsoGuard results are still pending were reported here as "not completed" by some sites

§Subject had a negative EG result and was scheduled for upper endoscopy for non-screening purposes

⸸Subject had a positive EG result and was referred for endoscopy, but refused scheduling of the procedure

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EsoGuard Results and Clinical Utility Evaluation

Of the 272 subjects with EC cell collection information, 242 received EG results by the time of data snapshot, although only 232 were documented in the study database. Among those, 229 also had a documented management decision from their ordering physician regarding referral for UE (Table 3A). Just under 30% of the EG results returned positive (29.3%, 68/232) and 65.5% (152/232) returned negative. Eight subjects (3.4%) had insufficient DNA quantity in their cell samples for EG analysis (QNS), and four (1.7%) cell samples were unevaluable due to other factors (e.g., contamination). Just over 30% of subjects (70/229) were referred to UE following their EG results; the remainder were not. According to the investigators, the reason for over 95% of their UE referral decisions was because of a positive (29.7%) or negative (65.9%) EG result.

EG results and their relationship to UE referral were evaluated by subject risk cohort (those either meeting ACG screening criteria or not) and presented in Table 3B. Three subjects with non-binary EG results (two QNS and one unevaluable) were pending endoscopy referral decisions. Two EG(+) subjects and one EG(-) subject with endoscopy referral decisions were missing risk factor and/or demographic information and therefore could not be classified into either the ACG vs. non-ACG cohorts; these subjects were excluded from counts within those cohorts but still contributed to analysis of the full study cohort. All (100%) of subjects with EG(+) results were referred for confirmatory UE. This was consistent across both risk cohorts. Only one subject with EG(-) result was referred for UE, and all others were not. One subject with an unevaluable result was referred directly to UE rather than repeating EG/EC.

Table 3B: EsoGuard Results and Endoscopy Referral Decisions by Risk Cohort

Physician Mgmt Decision: was the subject referred for UE?	**Overall EG results (n = 232)**		**Positive (n = 68⁘)**		**Negative (n = 152⁘)**		**QNS (n = 8*)**		**Unevaluable (n =4**)**	
	% (n/N)	**95% CI**	**% (n/N)**	**95% CI**	**% (n/N)**	**95% CI**	**% (n/N)**	**95% CI**	**% (n/N)**	**95% CI**
Full Study Cohort, among subjects with endoscopy referral decisions (n = 229§)										
Not referred	69.4% (159/229§)	[63.0, 75.3%]	0.0% (0/68)	[0.0%, 5.3%]	99.3% (151/152)	[96.4%, 100.0%]	100.0% (6/6)	[54.1%, 100.0%]	66.7% (2/3)	[9.4%, 99.2%]
Referred	30.6% (70/229§)	[24.7, 37.0%]	100.0% (68/68)	[94.7%, 100.0%]	0.7% (1/152)	[0.0%, 3.6%]	0.00% (0/6)	[0.0%, 45.9%]	33.3% (1/3)	[0.8%, 90.6%]
Cohort meeting ACG screening criteria, among subjects with endoscopy referral decisions (n = 169; 73.8%)										
Not referred	72.3% (120/166)	[64.8, 78.9%]	0.0% (0/44⁘)	[0.0%, 8.0%]	99.1% (112/113⁘)	[95.2%, 100.0%]	100.0% (6/6)	[54.1%, 100.0%]	66.7% (2/3)	[9.4%, 99.2%]
Referred	27.7% (46/166)	[21.1, 35.2%]	100.0% (44/44⁘)	[92.0%, 100.0%]	0.9% (1/113⁘)	[0.0%, 4.8%]	0.00% (0/6)	[0.0%, 45.9%]	33.3% (1/3)	[0.8%, 90.6%]
Cohort not meeting ACG screening criteria, among subjects with endoscopy referral decisions (n = 60; 26.2%)										
Not referred	63.3% (38/60)	[49.9, 75.4%]	0.0% (0/22⁘)	[0.0%, 15.4%]	100.0% (38/38⁘)	[90.7%, 100.0%]	N/A	N/A	N/A	N/A
Referred	36.7% (22/60)	[24.6, 50.1%]	100.0% (22/22⁘)	[84.6%, 100.0%]	0.0% (0/38⁘)	[0.0%, 9.3%]	N/A	N/A	N/A	N/A

QNS = DNA quantity not sufficient for EsoGuard analysis

⁘Two EG positive and one EG negative subject with endoscopy referral decisions did not have complete risk factor information and therefore were excluded from the counts for ACG vs. non-ACG cohorts, however contributed to counts for the full study cohort

§Three subjects with reported EG results were pending UE referral information i.e., difference between n = 232 subjects with EG results (all results, including QNS and unevaluable) and n = 229 with endoscopy referral decisions

*Two subjects pending referral information

**One subject pending referral information

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Table 4: Primary Clinical Utility Outcome – Provider Decision Impact

Analysis Set	Subjects with Binary EG Result	EG(+) subjects referred to UE	EG(-) subjects not referred to UE	Concordance between EG results and UE referral (95% CI)
		(95% CI)	(95% CI)	
Overall	**220**	**100.0% (94.7%, 100.0%)**	**99.3% (96.4%, 100.0%)**	**98.9% (96.9%, 100.0%)**
Site ID = 01	22	100.0% (29.2%, 100.0%)	94.7% (74.0%, 99.9%)	83.1% (51.1%, 100.0%)
Site ID = 02	42	100.0% (75.3%, 100.0%)	100.0% (88.1%, 100.0%)	100.0% (100.0%, 100.0%)
Site ID = 03	71	100.0% (81.5%, 100.0%)	100.0% (93.3%, 100.0%)	100.0% (100.0%, 100.0%)
Site ID = 05	85	100.0% (89.7%, 100.0%)	100.0% (93.0%, 100.0%)	100.0% (100.0%, 100.0%)

The primary clinical utility outcome of provider decision impact analyzed only the subjects with binary EG results and a documented physician decision on UE referral, of which there were 220 (Table 4). This primary outcome was analyzed on a study level and on a per-site level. The overall concordance between EG results and UE referral pattern was 98.9% (study level); all sites except one had 100% concordance.

Discussion

Despite well-established criteria defining patients at increased risk for BE and multiple published societal guidelines for screening, a significant diagnostic gap remains; most patients who could benefit from screening are not being screened [15]. When different modalities for BE screening were reviewed and compared – including traditional UE, transnasal endoscopy, video capsule endoscopy, and minimally invasive sampling devices combined with analysis of cellular markers – it was apparent those with the highest diagnostic accuracy (i.e., endoscopy) were also associated with the lowest transportability, patient convenience, or acceptance [16]. This supports the concept of a two-step process for improved BE diagnosis: the first step being a well-tolerated, highly sensitive, non-invasive triage test which is accessible for the larger, at-risk population; the second step would be a confirmatory test (for triage 'positive' patients only) with high diagnostic accuracy but lower convenience – namely UE with or without biopsy. Patient triage via non-endoscopic testing strategies has accumulated interest, with the most widespread literature available for CytoSponge, a swallowable sponge on a string, paired with immunohistochemistry (trefoil factor/TTF3) [17]. Comparative modeling analyses have even shown that use of this diagnostic approach in primary care settings can be cost effective [18]. In China, balloon-based esophageal cell collection has been successful in supporting cytology screening for esophageal cancer [19]. Aside from being the only commercially available non-endoscopic esophageal cell collection device on the U.S market, advantages of EsoCheck compared to the other devices include the unique, balloon-capsule design, which allows targeted cell collection and specimen protection. Specifically for diagnosis of BE, a disease in which cellular changes originate and are localized to the distal esophagus, balloon inversion within the EC capsule after targeted collection in the distal esophagus avoids cellular dilution and contamination as the device is removed through the upper esophagus and oropharynx. Additionally, as seen in CLUE, the EC cell collection process is fast, with a median cell collection time of only four minutes (note - the mean duration was skewed by the presence of one extreme outlier), and very well tolerated with less than four percent of patients unable to swallow the device; no patients reported complaints or complications to their physicians following the visit. This contrasts with sponge-based cell collection devices that take a minimum of 7-10 minutes for the gel capsule to dissolve in the stomach, and run the risk of string detachment [17, 20]. The EsoGuard Esophageal DNA Test, which utilizes targeted next generation sequencing and validated algorithms to detect abnormal DNA methylation patterns, in turn has significant advantages over cytology. Unlike cytology, which requires highly trained experts to accurately classify cells, the EG assay is automated, easily scalable, and not subject to inter-observer variability. As seen in the CLUE data snapshot, binary EG test results were available in approximately 95% of patients, which remains well within standards of biomarker tests performed in CLIA-certified laboratories. Patients included within this CLUE interim analysis accurately represent the target BE testing population as described by GI society guidelines, namely patients with multiple risk factors - the majority of which have chronic GERD of long-standing duration. Over 80% of the chronic GERD patients in the study were on acid suppressive medications, 81.6% of which reported good symptom control and would therefore have been less likely to seek out or been referred for UE. The observed EG positivity rate of 29.3% may seem high compared to reported BE prevalence rates of 5-15% cited in the literature, however this number is reasonable in the context of the higher risk study population (majority of subjects with 4 or more established BE risk factors). Published BE

prevalence rates are also likely an under-reporting of true disease prevalence due to historically low rates of screening, leading to under-diagnosis [21, 22]. Indeed, literature shows that less than 20% of patients in the U.S who are diagnosed with EAC have any preceding diagnosis of BE, and only 10% of high-risk individuals undergo endoscopic BE screening [23, 24]. The cause is likely multifactorial, including lack of any characteristic constellation of symptoms associated with BE, poor patient understanding of their own disease risk, and fears around the discomfort or inconvenience of UE [25]. Office-based, non-endoscopic testing with EG/EC can address these patient concerns by improving accessibility and minimizing invasiveness. Given the intended utility of EG as a high-sensitivity triage test, it is expected that the EG positivity rate should be higher than true disease prevalence, so as not to risk missing any patients with disease.

The 98.8% concordance between EG results and UE referral demonstrate that CLUE physicians are consistently utilizing EG as a triage to endoscopy. 100% of EG(+) subjects were referred for further UE work-up, and 99.3% of EG(-) received no additional diagnostic evaluation. This is consistent with the physician's own self-reporting, with >95% of their documented referral reasons being either a negative or positive EG result (Table 3A). This remained true even for the cohort of patients that specifically met ACG guideline criteria for screening. The ACG screening guidelines for BE are arguably some of the more stringent compared to those of other GI societies, given their requirement that all patients have chronic GERD (defined as five or more years of frequent symptoms) and at least three additional risk factors [26]. These patients could be clinically justified in proceeding straight to UE for BE screening, however in all except one individual with negative EG results (112/113, 99.1%), triage with EG was able to save them from the more burdensome, uncomfortable, and higher-risk diagnostic procedure. The singular subject with a negative EG results who was sent for UE did so for non-screening purposes; the UE was performed for pre-operative workup of planned anti-reflux surgery (Table 3A and 3B). This demonstrates provider confidence in negative EG results and the ability to rule out BE. Results of the clinical utility analysis are unsurprising, given that specialty Societies including the AGA and ACG have already recognized non-endoscopic cell collection paired with DNA biomarkers as an acceptable approach to initial BE screening [4, 13]. The focus of this manuscript was on real-world provider decision impact, and we recognize that absence of patient outcomes may be deemed a limitation. However, the intent of technologies like EG/EC is to facilitate early diagnosis through more widespread testing of high-risk individuals, and increased patient and provider awareness of BE. The intent is not to change standards of care following establishment of a diagnosis. There are clear guidelines for management of patients once diagnosed - including timing of surveillance and indications for ablative therapy - which are expected to improve immediate and long-term patient outcomes [4, 27, 28]. It is not within the scope of a triage test like EG or studies like CLUE to ensure patient or provider compliance with those guidelines. Another potential limitation of this study is the small number of enrolling sites (n=4) and investigators; the number of sites and physicians is planned to double over the remainder of the study. It is important to note that despite the small number of investigators, multi-disciplinary representation was still achieved, with three different specialty types. In short, the early experience in CLUE appears to support EG as an effective triage to UE, which can be used in both primary care and specialty settings to assist in physician decision-making. This approach could facilitate increased testing of patients at high risk for BE/EAC, while also focusing UE resources on those patients with the highest pre-procedure probability of disease.

Conclusions

Review of data from the first snapshot of the CLUE study demonstrates that physicians who have adopted EG/EC into their clinical practices are reliably utilizing EG as a triage to UE for diagnostic evaluation of patients at high risk of BE/EAC. EG(+) individuals are consistently referred for confirmatory UE, whereas EG(-) subjects are being spared the more invasive test.

Conflict of Interests

D.L, A.F, S.M, and P.S.B declare no conflicts of interest. V.T.L, B.J.D, and L.A are executive members of PAVmed Inc., of which Lucid Diagnostics Inc. is a subsidiary, and own stock and/or options in the parent company. S.V is an executive member of Lucid Diagnostics Inc. and owns stock and/or options in the company.

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