

Diagnosing Diarrhea Predominant Irritable Bowel Syndrome (IBS-D): A Real-World Study to Assess Resource Utilization

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INTRODUCTION

- IBS is a common gastrointestinal disorder affecting over 10% of the US population.¹ A challenge in diagnosing patients with diarrhea-predominant IBS (IBS-D) has been the absence of biomarkers; a positive diagnostic strategy as compared to a strategy of exclusion is a goal^{2,3}

OBJECTIVES

- A real-world study was initiated at two sites to evaluate the impact of a non-invasive 2nd generation blood test biomarker (ibs-smart^{®4}) in terms of reducing the need for further testing.
- The goal of the retrospective analysis is to determine the impact of a novel 2nd generation blood test on the costs associated with diagnosing gastrointestinal disorders in patients presenting with symptoms suggestive of IBS-D and IBS-D/M.

METHODS

- Chart reviews were conducted for 176 subjects meeting the inclusion/exclusion criteria to identify their testing and gastroenterologist office visit history.
- Costs included in the study were for 18 diagnostic tests including the 2nd generation blood and lactulose hydrogen breath test intended to detect SIBO (small intestinal bacterial overgrowth), plus visits to the gastroenterologist's office.
- Costs for most tests were then calculated based on CPT codes using medical reimbursement data from the New Hampshire all-payer claims database with 2022 dates of service.
- The data set contains commercial and Medicare (supplement and advantage plans) claims from large payers within the state and includes billing and payments made by insurance companies and members.
- In a few cases, tests could not be found in the claims data, so other sources like MDsave and manufacturer's websites were used.
- The same cost for a resource was applied to both cohorts
- Nearest neighbor propensity matching was performed on key baseline variables including age, whether they had MCAS or IBS-D on their first visit, whether they were referred, and whether their first visit was before 2019, since the 2nd generation blood test became available in late 2018.
- After removing outliers from the dependent variable of costs, 58 subjects receiving the 2nd generation blood diagnostic test were compared to 58 matched control subjects not receiving the diagnostic test.
- Descriptive statistics were used to identify independent variables representing significant variance between cohorts that are related to a diagnosis of IBS.

Table 1. Inclusion and Exclusion Criteria

Inclusion Criteria	Exclusion Criteria
18 or over upon presentation to the site	Confirmed pregnancy at the time of presentation to site
Presented with some or all of the following symptoms: abdominal pain, stomach cramping, gas, bloating, chronic diarrhea, alternating diarrhea, and constipation	Presented with alarm symptoms (eg, fever, blood in stool, vomiting with blood)
Have a confirmed diagnosis of any gastrointestinal disorder(s)	
Have at least three visits and three months of follow-up	

Table 2. Patient Characteristics before and after Propensity Score Matching

	Before Propensity Score Matching		After Propensity Score Matching	
	No 2 nd Generation Blood Test (N=115)	2 nd Generation Blood Test (N=58)	No 2 nd Generation Blood Test (N=58)	2 nd Generation Blood Test (N=58)
Age (Mean)	52.9	48.3	47.8	48.3
History Before 2019 (%)	72.2%	34.5%	51.7%	34.5%
MCAS First Visit (%)	7.8%	0%	0%	0%
IBS D First Visit (%)	7.8%	3.4%	5.2%	3.4%
Referred (%)	87.8%	72.4%	79.3%	72.4%

RESULTS

- The mean age was 48 years old, 80% female. Patients had an average of 3.7 tests and were seen by the gastroenterologist for 2.6 years. The most common tests were colonoscopy (49.1%), Upper Endoscopy (31.0%), and lactulose breath test (50.8%). Less frequent tests include capsule endoscopy, c-reactive protein, celiac panel, and CT scan.
- SIBO, diarrhea, and migraine were the independent variables used in the model to determine the effect that 2nd generation blood test has on the costs associated with diagnosing gastrointestinal disorders in patients presenting with symptoms suggestive of IBS-D/M.
- Descriptive statistics show that the 2nd generation blood test group was diagnosed with SIBO and had diarrhea more often than the control group. Subjects in the 2nd generation blood test group were less likely to have migraines than the control group.
- The GLM (Gamma(link = "log")) showed the 2nd generation blood test and SIBO were the most important factors for testing and office visit costs with both being statistically significant. The 2nd generation blood test was associated with lower costs while SIBO was associated with higher costs.
- From a cost perspective, the model shows an incremental savings of \$526 when a subject had the 2nd generation blood test.

Table 3. Independent Variable T-Tests

Diagnosis/Symptom	No 2 nd Generation Blood Test		2 nd Generation Blood Test		P
	N	%	N	%	
SIBO	24	41.4%	42	72.4%	<.001
Diarrhea	34	58.6%	44	75.9%	<.05
Migraine	19	32.8%	12	20.7%	<.15

Table 4. GLM Model

Estimate	Std.	Error	t	value	Pr(> t)
(Intercept)	7.9	0.1	68.9	0.00	***
2 nd Generation Blood Test	-0.2	0.1	-2.0	0.05	*
SIBO	0.4	0.1	3.3	0.00	**
Diarrhea	0.2	0.1	1.7	0.09	.
Migraine	-0.2	0.1	-1.8	0.07	.

CONCLUSIONS

- Colonoscopy and other invasive tests continue to be utilized adding to the costs and discomfort of patients.
- Novel 2nd generation non-invasive blood test group showed a significant reduction in diagnostic testing cost compared to the control group.
- Novel breath test is currently being evaluated and may show promise in terms of reduction of downstream invasive testing and targeted treatment which may lead to lower system costs and accurate diagnosis.

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