P1144 (S0507). SIBO Diagnosis: Clinical Survey of Practice Patterns, Unmet Needs, and Perception of a Novel Ingestible Diagnostic Capsule

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Background & Aim

- Small intestinal bacterial overgrowth (SIBO) syndrome has clinical overlaps with irritable bowel syndrome (IBS), but is a distinct disorder, making its accurate diagnosis critical.
- Current diagnostics are invasive, costly, and/or have low reliability.
- A novel ingestible diagnostic capsule called the Smart Capsule Bacterial Detection System (SCBDS) is being developed to address this unmet medical need and to understand the performance characteristics required for product adoption.
- The objectives of this clinical survey study was to understand the following:
 - How clinicians currently diagnose SIBO and their concerns regarding the method and treatment of this condition
 - Their view of the potential opportunity for a novel diagnostic test
 - The clinicians' preference for the product concept and potential utilization in practice

Methods

Phase 1: Qualitative phone interviews with seven Gastroenterologists (GIs) and three GI experts on SIBO was done to explore their current approach to diagnosis and treatment of SIBO.

Phase 2: Based on Phase 1 responses, a quantitative interview with 90 GIs who typically see 150+ patients per month was done including at least 40 IBS patients.

Respondent Demographics

Fig 1. Of the GIs surveyed, 2/3 work in a private office group practice, of which about 3/4 are single specialty practices % of Private Offices Group Practices: Single Specialty



Results

Fig 2. The most common diagnostic workup for SIBO is breath testing and empiric antibiotic therapy. Few providers perform "gold standard" small bowel aspirations and culture



Fig 3. Most Gls were either unsatisfied or very unsatisfied with the currently available options to diagnose SIBO.

Satisfaction with Current Available Options to Diagnose SIBO (Ratings on 1-10 scale, 1 = "Extremely Unsatisfied", 10 = "Extremely Satisfied")



Fig 4. The greatest unmet needs of practicing Gls are insufficient accuracy with SIBO diagnostic tests and difficulty in interpreting the results. Unmet Needs for Diagnosing SIBO

(Respondents selected 3 options)

Insufficient accuracy in current test options 7% 58% Lack of clear, easy to interpret results 48% Lack of outcomes data 13% 6% 19% 38% High out of pocket costs 16% 12% 8% 36% 33% Access to test 16% 6% 12% Significan insurance hurdles to ordering 6% 12% 14% 32% Lack of clinical impact 3% 11% 14% 29% High risk of contamination 4% 7% 12% Long turnaround time on test results 8% 3% 12% Over the state of the state 2nd Greatest Greatest



Fig 5. The accuracy of breath testing results is rated poorly by GIs.

Fig 6. While many GIs use empiric antibiotic therapy, most indicate that it is not diagnostic, and they have concerns about antibiotic resistance.

Important Disadvantages of Using Empiric Antibiotic Therapy for Suspected SIBO Patients (Respondents selected 3 options)



Fig 7. The SCBDS was viewed favorably against both endoscopic aspiration and culture and hydrogen breath testing.

Test Complemented / Replaced by Product S for Diagnosing SIBO





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Product S (SCBDS) Description





- Product S, a Smart Capsule Bacterial Detection System (SCBDS), is indicated for use as an aid in the clinical evaluation of patients with symptoms suggestive of Small Intestinal Bacterial Overgrowth (SIBO).
- The Capsule is the same size as The PillCam Colon (11 x 31mm) and can autonomously identify its location in the GI tract.
- The Capsule takes a sample of GI fluid from the jejunum, measures total bacterial concentration, and transmits data wirelessly to a receiver worn by the patient.
- Results can be downloaded immediately and reviewed on your computer.
- The receiver is disposable, and there is no need for dedicated hardware as with other products.
- Initial assessment of the performance of the bacterial quantification assay in Product S, compared with endoscopic aspiration and culture, yielded a sensitivity of >80% and a specificity of >80%.

Conclusions

- Current tools for diagnosing SIBO are suboptimal.
- H2 breath test and empiric antibiotic therapy are widely used; however, most GIs are dissatisfied with both options.
- Endoscopic aspiration and culture is not commonly available.
- The initial performance of the assay were viewed favorably by GIs and superior to breath testing, leading in part to their preference for Product S.
- A novel diagnostic ingestible capsule is viewed favorably and has the potential to replace both endoscopic aspiration and H2 breath testing as the preferred diagnostic tool for suspected SIBO patients.