3 years and 1 million patients: safety data on caraway oil and L-menthol with site specific targeting (COLM-SST®) for Functional Dyspepsia

Brian Lacy, PhD, MD, FACG[1]; Michael Epstein, MD, AGAF, FACG[2]; Patrick Corsino, PhD[3]

1. Mayo Clinic, Jacksonville, FL, United States; 2. Digestive Disorders Associates, Annapolis, MD, United States; 3. IM HealthScience LLC, Boca Raton, FL, United States

BACKGROUND

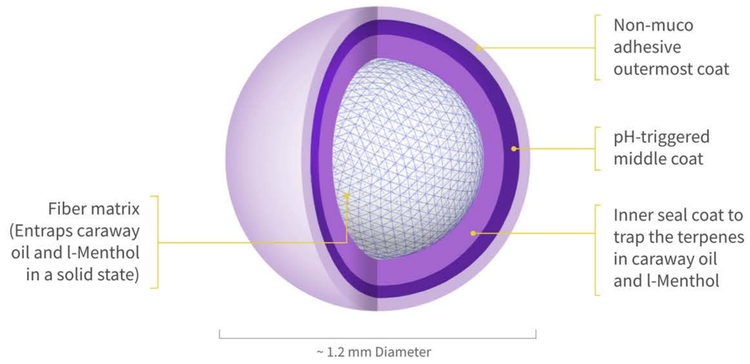
Functional Dyspepsia (FD) is a common functional GI disorder. The estimated prevalence is 10-30% worldwide[1-3]. There are currently no FDA-approved medications for its treatment. Proton pump inhibitors (PPIs) are often prescribed off-label although are not very effective. In addition, long-term use of these drugs has been associated with serious health concerns. Prokinetics are also often used off-label. However, many are associated with side effects[4-5] (e.g. metoclopramide). A safe, effective, and readily available treatment option for FD is greatly needed.

We describe the results of an important 36-month post-marketing analysis of COLM-SST, an over-the-counter medical food demonstrated to be safe and efficacious in an RCT[6]. Previous RCTs showed that the combination of caraway oil and peppermint oil improves FD symptoms. Caraway oil plus L-menthol (the major component of peppermint oil) with site-specific targeting (COLM-SST) is a novel delivery system of triple-coated, solid-state microspheres designed to target the duodenum, the main center of disturbance in FD. This study was conducted to report on the overall safety profile of COLM-SST and to determine if unexpected patterns of side effects emerged.

METHODS

A call-in number for reporting adverse events (AEs) was provided on all boxes of COLM-SST. An independent call center with pharmacovigilance-trained health care personnel, in accordance with the FDA and global regulatory guidelines on properly reporting AEs, was retained to receive and record customer AEs. Data was collected and processed from July 2016 to July 2019.

Figure 1. Triple-coated microsphere technology of COLM-SST®



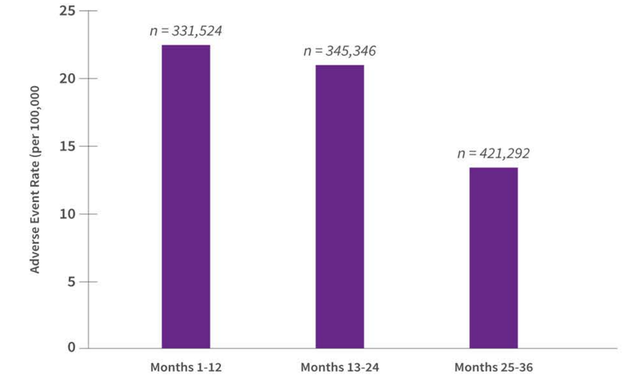
RESULTS

- An estimated 1,098,162 patients used COLM-SST during the surveillance
- No serious AEs were reported
- The rate of non-serious AEs was low, with only 205 events received (from 179 patients), a rate of 0.019%
- The top-reported, non-serious AEs were abdominal pain/discomfort/distension (35; 0.0032%), which are consistent with the pattern of commonly reported presenting symptoms of FD, and dyspepsia (22; 0.0020%), the underlying condition itself (Table 1)
- No pattern of AEs associated with drug interactions was identified.

Table 1. Most commonly reported adverse events

System Organ Class	MedDRA Term	Cumulative AEs Months			Individual AEs Months		
Gastrointestinal Disorders	Dyspepsia	9	10	22	9	1	2
	Diarrhea	4	7	13	4	3	6
	Headache	5	9	11	5	4	2
	Nausea	3	6	11	3	3	5
	Abdominal distension	4	7	10	4	3	3
	Abdominal pain upper	3	6	9	3	3	3
	Throat Irritation	4	6	9	4	2	3
	Abdominal discomfort	2	7	8	2	5	1
	Abdominal pain	4	7	8	4	3	1
Skin and Subcutaneous Tissue Disorders	Pruritus	1	4	6	1	3	2
TOTAL		**75**	**148**	**205**	**75**	**73**	**57**

Figure 2. Adverse event rate for COLM-SST by year



CONCLUSIONS

36 months of monitoring in-market, real-world use of COLM-SST for the treatment of FD demonstrates an extremely low rate of self-reported AEs. Interestingly, the number and rate of AEs over time has decreased (Fig 2). These data, combined with earlier RCT data[6], indicates that COLM-SST is a safe and effective therapy for FD, and is a viable alternative to PPIs and prokinetics.

REFERENCES

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DISCLOSURES

- Brian E. Lacy, PhD, MD: Scientific advisory board: Ironwood, Salix, Covidien, IM HealthScience, LLC
- Michael S. Epstein, MD, AGAF, FACG: Chief Medical Advisor, IM HealthScience, LLC
- Patrick Corsino, PhD: Director of Product Development, IM HealthScience, LLC