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What is the SmartPill®?

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Abstract

The SmartPill® is a new, noninvasive technology to evaluate the gastrointestinal tract. It is a nondigestible capsule that migrates through the gastrointestinal tract to measure pH, pressure, and temperature. It was approved by the FDA in 2006 for the evaluation of colonic transit time in patients with chronic constipation and to evaluate gastric transit time in patients with suspected gastroparesis. Other currently used gastrointestinal monitoring systems have some disadvantages, and the SmartPill® is suggested as an alternative. The SmartPill® has also been used for research purposes in various studies and has the potential to be used in diagnosis and monitoring of other gastrointestinal diseases. The aim of this article is to evaluate the clinical significance of the SmartPill® by comparing it to other previous gastrointestinal monitoring methods, examining the FDA approved indications, assessing other possible uses for it and providing health care professionals with key counseling points for patients.

Key Terms

Ambulatory; Constipation; Gastric Emptying; Gastrointestinal Motility; Gastroparesis; Monitoring

Introduction

The SmartPill®, or wireless motility capsule (WMC), is a relatively new, noninvasive gastrointestinal (GI) monitoring device.¹ It comes in the form of a capsule and can be used to measure pressure, pH and temperature in the GI tract. Once it is ingested, the WMC monitors conditions in the GI tract as it travels through the body until it is excreted naturally in the feces.² The WMC was developed by the SmartPill® Corporation based in Buffalo, New York, and successfully received U.S. Food and Drug Administration (FDA) approval in 2006 to market in the United States.³ When funds to cover the production and development costs were exhausted, the SmartPill® Corporation was sold to Given Imaging, an Israeli company that develops similar devices, through which the SmartPill® is currently made available.⁴

Why should pharmacists be familiar with the WMC?

- The WMC has various applications for research on the effect that drugs and disease states can have on GI motility.
- Patients and doctors may approach pharmacists with questions about the WMC.
- It is important to understand new monitoring methods so that they can be compared to current methods in order to recommend the best procedure for patients.
- To help improve the care of patients.

This article will highlight the important aspects of the WMC and compare it to several other GI monitoring methods available. Current FDA indications of WMC will also be examined, as well as the applications for research and potential future uses. Finally, important counseling points for pharmacists regarding the WMC will be reviewed.

About the SmartPill®

The WMC is a nondigestible, disposable capsule.¹ Its size is 26 mm by 13 mm, which is slightly larger than a multivitamin tablet. It contains sensors that measure pH, pressure and temperature as it travels through the GI tract. The range of the pH sensor is 0.5 to 9.0 (accurate to ± 0.5), the pressure range is 0 to 350 mmHg (accurate to ± 5 mmHg), and the temperature range is 25 to 49°C (accurate to $\pm 1^\circ\text{C}$).⁵

The capsule uses amplitude-shift keying (ASK) modulated radio frequency signals of 434 MHz to transmit the data gathered from these sensors to a portable receiver (sized 14 cm by 11 cm by 3 cm).^{5,6} The receiver is worn on either a belt clip or lanyard by the patient throughout the procedure.¹ After the test, the receiver is connected to a docking station that downloads the data onto a computer with MotiliGITM Software. The program analyzes the results and converts them into a printable report.^{6,7}

Specifically, the WMC can measure and differentiate between gastric emptying time (GET), small bowel transit time (SBTT), combined small and large bowel transit time (SLBTT), colonic transit time (CTT) and whole gut transit time (WGTT).⁶ Figure 1 shows a sample of the data obtained from the WMC and its interpretation of GI transit times.⁸

Cassilly and colleagues determined the WMC usually empties from the stomach during phase III migrating motor complexes (MMC) that follow the end of the fed state by comparing it with data from gastric emptying scintigraphy (GES) and antroduodenal manometry.⁹ This confirmed that the WMC mimics the emptying pattern of nondigestible solids, rather than digestible foods. Other studies found varying levels of correlation, so the mechanism needs further studies to be fully understood.

The WMC is primarily used in the setting of a clinic or physician's office as a GI motility monitoring test to diagnose motility disorders, such as gastroparesis (determined by delayed GET) and chronic constipation (using CTT or SLBTT as a surrogate in cases of undetermined CTT).^{1,6} Usually, the WMC test is prescribed when the patient is experiencing unexplained GI symptoms including nausea, bloating, constipation, abdominal pain and/or vomiting.¹ By measuring GI transit times, it is possible to more accurately diagnose and treat the disease and thus eliminate much trial and error.

One limitation of the WMC is its relatively large size, which makes it difficult to swallow, as well as the possibility that it can be temporarily wedged in the stomach, leading to prolonged GET and WGTT.¹⁰ Other limitations include the fact that the receiver must be kept in close proximity throughout the procedure and the limited battery life. Also, if the capsule exit cannot be confirmed due to technical issues of the receiver, in which case an X-ray is required, this will add extra costs and difficulty for the patient. These issues must be carefully considered before deciding on the best option for the patient.

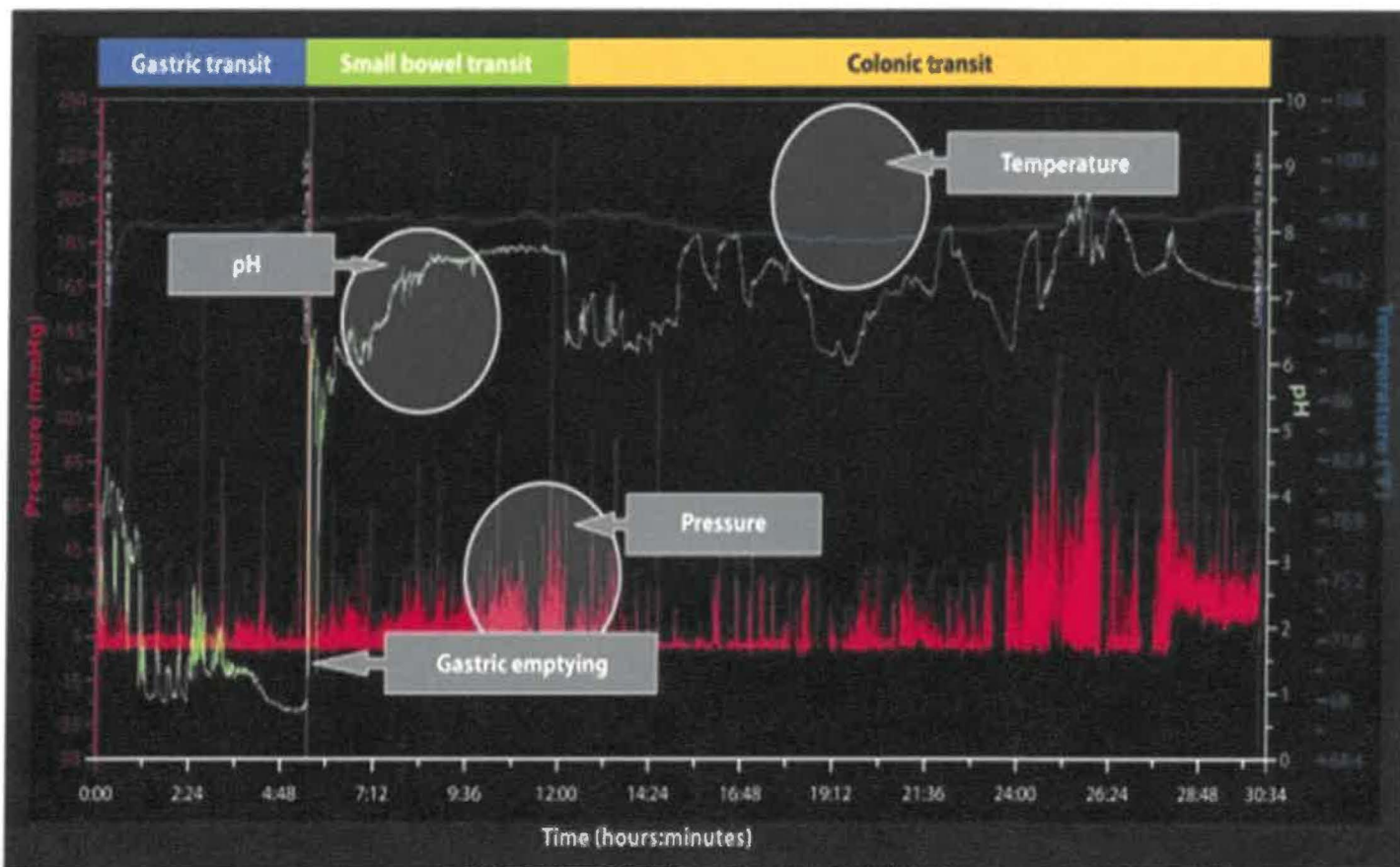
How to use the SmartPill®

Given Imaging has a patient education pamphlet that instructs patients on how to prepare for the test and about the administration of the WMC.² Eight hours before the test, patients are instructed not to eat or drink anything except water. This is unlikely to be an issue since the WMC is usually administered in the morning, so the fasting prior to the test is simply overnight.

When the patient arrives at the clinic or the physician's office for the appointment (which typically lasts only 30 minutes), they are given a SmartBar® to eat before swallowing the capsule.² The SmartBar® is a standardized nutrient bar containing 66 percent carbohydrates, 17 percent protein, 2 percent fat and 3 percent fiber.¹¹ It stimulates the post-prandial state of the stomach so that each patient has a consistent starting point for the administration of the WMC to allow an accurate measurement of GI transit times.² Once the patient has eaten the SmartBar®, the physician activates the WMC by placing it on the activation fixture.¹² The WMC is then ingested and the patient is given the receiver that records the data from the capsule.² At this point the patient is free to leave and resume their normal daily activities as long as they fast for six hours after the administration of the WMC and wear the receiver. Even when sleeping or bathing, the receiver should be kept no more than a few feet away from the patient to allow for complete data collection.

The test lasts about three to five days or as long as it takes for the WMC to be excreted.² If not excreted within five days,

Figure 1. Sample Data From a Wireless Motility Capsule.



Sample of pH, temperature and pressure data collected by the wireless motility capsule (WMC) and the three main transit times that can be determined by its utilization: **gastric emptying time, small bowel transit time and colonic transit time.**⁸ Upon ingestion, WMC detects temperature increase to body temperature. The GET is determined by the abrupt rise in pH ≥ 2 , which signals the WMC's exit from the acidic stomach into the basic intestine. The SBT is measured as the time period from GET to a second major pH change (abrupt drop ≥ 1 pH units), which represents WMC exit from the ileum and entrance into the relatively more acidic cecum. The CTT is the time from WMC entry into the cecum to its excretion from the body, detected by an abrupt and sustained temperature drop. Used with permission from: Saad RJ, Hasler WL. A technical review and clinical assessment of the wireless motility capsule. *Gastroenterol Hepatol* (N Y). 2011;7(12):795-804.

the battery life of the capsule/receiver set may expire, resulting in incomplete data collection. Patients should allow bowel movements to remain in the toilet for five minutes to allow the capsule to detect the temperature change once it has been excreted, which will trigger the indicator light on the receiver.¹⁰ After one week, if neither the receiver nor the patient can confirm the passage of the capsule, the patient may have to undergo an abdominal X-ray to ensure excretion.¹¹ Once data collection is finished, the patient returns the receiver to the physician's office where the results can be downloaded and analyzed.² It is not necessary for the patient to retrieve the capsule.

Comparison with Other Methods

Scintigraphy

Scintigraphy and radiopaque markers have commonly been used to evaluate whole gut transit.¹³ Whole gut transit scintigraphy (WGTS) involves a three to four day test. Patients are required to stop medications that may have effects on GI motility for 48 hours before the test. Patients then ingest two large scrambled eggs labeled with 500 μ Ci of 99m-Tc sulfur colloid served between two pieces of toasted white bread, and 300ml of water containing 125 μ Ci of 111-In-DTPA. The data is obtained by a large field of view camera with a medium energy collimator and a nuclear medicine computer.¹⁴ Although scintigraphy involves minimal exposure to radiation and is able to assess whole gut transit, it is expensive and has a long duration of time to study, making it unsuitable for practice. A study by Maqbool and colleagues suggested that the WMC can be the next improved method for assessing GI motility. The study compared the whole gut transit of 10 healthy subjects using scintigraphy and the WMC simultaneously, and the transit time between the two methods was strongly correlated, indicating that the WMC gives comparable results to scintigraphy.¹³ Furthermore, a study by Cassilly and colleagues also observed the strong correlation between scintigraphy and the WMC for measuring GET. Their experiments were conducted with 15 normal subjects receiving antroduodenal manometry, scintigraphy, and the WMC.⁹ Because the WMC is convenient and requires less work by an administrator as compared to scintigraphy, it may represent a superior choice as an examination tool due to its similar level of accuracy.¹³

Antroduodenal Manometry

The migrating motor complex (MMC) is one of the most studied and well-known patterns of GI motor function to detect various GI disorders, such as irritable bowel syndrome, functional dyspepsia, gastroparesis and constipation.¹⁵ Phase III MMC in the stomach and small intestine has been a challenging region to evaluate, and the standard method of antroduodenal manometry is invasive in nature. The instrument requires cleaning out of the intestinal tract to insert the water perfused or solid state catheter to measure the intraluminal pressure.^{16,17} In contrast, the WMC's noninvasive characteristic can be an alternative method to detect phase III MMC. A study from Brun and colleagues conducted a comparative analysis of phase III MMCs in the stomach and small bowel by administering the WMC and antroduodenal manometry concurrently to 18 patients. The outcomes of the

study revealed that the WMC was able to detect with good precision the phase III MMC, which was identified as high amplitude contractions. In the study, the researchers stated that the WMC's characteristic of freely floating inside the gut might have resulted in differences in luminal pressures, requiring different parameters for interpretation. However, this limitation of needing a new set of interpretation tools can outweigh the benefits for the noninvasive nature of the WMC when compared to the standard test of the antroduodenal manometry.¹⁵ Additionally, antroduodenal manometry has disadvantages not shared with the WMC. A study by Hasler and colleagues indicated that cleansing the colon with a lavage solution to perform antroduodenal manometry might disrupt physiological conditions of fecal retention, which lead to inaccurate assessment in constipation studies. Furthermore, manometry requires specialized equipment and manpower, making it a challenge to use frequently in a clinical setting.¹⁷ The WMC technology has shown its potential in the Brun and colleagues study to extend from its FDA indicated uses in the diagnosis of constipation and gastroparesis to accurately detect phase III MMC.

Radiopaque Markers

Even though radiopaque markers (ROMs) have been used traditionally to measure CTT, this technique requires radiation, and its lack of standardization and compliances makes it a technique that some health care professionals are reluctant to use. The ROMs are plastic beads or rings that are packaged in a capsule, and a single capsule technique or a multiple capsules technique is used to obtain the data.¹⁸ The single capsule technique is when the patient ingests a single capsule followed by several abdominal X-rays until all markers are excreted, or a single abdominal X-ray is taken on day 5. Because this method is time-consuming and the patient is exposed to high levels of radiation, the multiple capsules technique is preferred, where the patient ingests one capsule a day for three days, and abdominal X-rays are taken on day 4 and day 7 or only on day 7.

A ROM test is not capable of analyzing regional gut transit, and performing the test sometimes requires multiple visits.¹⁹ In order to suggest an alternative method to monitor CTT, a study by Rao and colleagues utilized the WMC and ROM to compare CTT, WGTT, SBTT and GET between 78 constipated patients and 87 healthy control patients for five days. The study was designed to assess the ability of the WMC to differentiate between CTT and WGTT and distinguish normal and slow CTT. Furthermore, the study compared the accuracy of the information with that of the ROM method. The study observed a delay in GET, CTT and WGTT with constipation patients. The diagnostic accuracy to determine constipation exhibited specificity of 0.95 and reasonable sensitivity of 0.46 with the WMC, and 0.95 specificity and 0.40 reasonable sensitivity for ROM, which demonstrated a great congruency between these two tests. Additionally, the high specificity indicated the WMC's ability to distinguish between normal and slow CTT, and its continuous and more direct measure of CTT may be able to indicate the severity of slow transit constipation in the future. Because the WMC does not require radiation and has results agreeable with ROM, it has demon-

strated its potential to be a comparable measurement method for CTT and become a standardized technique.

SmartPill® Uses

The WMC was approved as a GI motility monitoring device in 2006 according to the FDA 510K statement, having met all the clinical testing and safety criteria for such devices.³ It is used mainly to diagnose gastroparesis, but it can also be used to diagnose chronic constipation. Off-label uses include research analyzing how certain diseases and drugs affect GI motility and conditions. The WMC also has the potential to be utilized to diagnose diseases involving hypersecretion of acid.²⁰

Approved Indications

Gastroparesis

Gastroparesis is a chronic GI disorder in which the emptying of the stomach is delayed for reasons other than a physical obstruction.⁵ Patients may experience nausea, vomiting, bloating, abdominal pain and dyspepsia. Due to the fact that these symptoms are common to many GI disorders, it can be difficult to pinpoint the exact cause based only on the clinical presentation. A prospective, multicenter study by Kuo and colleagues examined the ability of GET measured by the WMC to differentiate between healthy and gastroparetic subjects compared to GES.

The study involved 87 healthy subjects and 61 subjects with gastroparesis.⁵ All patients were simultaneously given the WMC to assess GET and a [99mTc]-SC radiolabelled meal to measure percent of meal retained at 30 minute intervals by GES. The WMC was taken first, followed by the completion of the radiolabelled meal within 20 minutes of capsule ingestion. A correlation greater than 0.7 was considered to be significant. Results found GET (measured in minutes), GES-2h, and GES-4h (measured in percent of meal retained in the stomach) to be significantly different in healthy subjects as compared to gastroparetic subjects (p -value <0.05). The GET was most strongly correlated with GES-4h (0.73), which was greater than the target 0.7 for significance. The correlation between GET and GES-2h did not reach statistical significance (0.63). Both GET and GES-4h were shown to be clinically useful for diagnosing gastroparesis, so the WMC could be considered a viable replacement for GES.

Chronic Constipation

There is little known about colonic motility in normal, constipation, and constipation-predominant irritable bowel syndrome (C-IBS). The study from Hasler and colleagues conducted an experiment to characterize regional differences in colon pressure, relate motor differences in constipation to colon transit and quantify the role of irritable bowel syndrome (IBS) in altered contractility with constipation using the WMC.¹⁷ Because the capsule continuously measures luminal pH, pressure and temperature, it was used to obtain a greater understanding of the relationship between colon motor activity and constipation, as well as to differentiate C-IBS from constipation not related to IBS. The study recruited 53 healthy and 36 constipated subjects. Twelve of the constipated participants had C-IBS, and 24 had functional constipa-

tion. The study concluded that colon pressure activity is active distally, rather than proximally, in the control group. Due to IBS, constipated patients with normal or moderate slow transit demonstrated an increase in motor activity, which showed differences in transit and motility among different subtypes of constipated patients.

The study discussed some limitations of WMC technology.¹⁷ First, the capsule has one pressure sensor, which did not allow it to distinguish between mixing and propulsive motility, identify high-amplitude propagating contractions or differentiate motor artifact from luminal contractions. Second, due to the capsule's size larger than stool, the capsule was not managed physiologically in the body. Some studies have observed that the WMC moved faster in the colon than small particles or liquids. Finally, it is difficult to detect the position of the capsule accurately, except when the capsule was in ileocecal transit and before excretion. Despite its weaknesses, the WMC may have potential future use in testing responsiveness to laxatives in different patients. Also, it can be a useful method to decide treatment options for difficult constipation cases.

Research Purposes

Spinal Cord Injury

Patients who have experienced spinal cord injury (SCI) sometimes experience a disruption in their GI function.²¹ It can be difficult to monitor and research their condition with traditional testing methods due to the invasive nature of existing tests or necessity to alter lifestyle during the testing period, both of which can potentially affect results. Williams and colleagues studied the effects of SCI on GET, CTT and WGTT using the WMC as their GI motility monitoring device. Their goal was to determine if the WMC was a viable option for monitoring SCI patients and evaluate their GI function.

The study enrolled 20 SCI patients and 10 healthy subjects.²¹ The SCI patients had complete or incomplete paraplegia and tetraplegia for more than six months as well as abnormal bowel movements. The SCI group had prolonged GI transit times (GET: 10.6 ± 7.2 hours, CTT: 52.3 ± 42.9 hours, WGTT: 3.3 ± 2.5 days) compared to the healthy patients (GET: 3.5 ± 1.0 hours, CTT: 14.2 ± 7.6 hours, WGTT: 1.0 ± 0.7 days) with p -value less than or equal to 0.01. These results supported evidence from previous studies that used more invasive methods that indicated SCI patients had delayed GI transit times. None of the subjects had difficulty swallowing the WMC, and they reported no complications or side effects as a result of taking the WMC. The study concluded that the WMC was most likely a safe and effective method for GI monitoring in patients with SCI.

Medications

Certain drugs can have an impact on GI motility. Rozov-Ung and colleagues performed a crossover study to test the ability of the WMC to evaluate the effect of erythromycin IV 150 mg versus morphine IV 0.05 mg/kg versus normal saline IV on GET and motor activity.¹¹ Erythromycin is well known to decrease GET while morphine increases GET.

The study included 15 healthy adults who were administered each course of therapy, in random order, on three separate occasions at least one week apart.¹¹ The GET for erythromycin was significantly faster than saline (p -value < 0.001), while GET for morphine was somewhat slower compared to saline (p -value = 0.11). Contractility was not significantly different when comparing morphine to erythromycin (p -value = 0.14) or saline (p -value = 0.12). The WMC successfully detected expected changes in GI motility caused by erythromycin and morphine, and thus may be a valuable tool for researching the effects of other drugs on GI motility.

Dietary Fiber

Dietary fiber is well known to affect GI motility, but for many years the only methods to quantify the effect were either invasive or involved radiolabeled food.¹⁰ Timm and colleagues performed a controlled, crossover trial to determine whether the WMC could measure the difference in GI transit times between a wheat bran and a low fiber control diet.

Ten healthy subjects were enrolled in the study.¹⁰ Each subject completed both dietary interventions. These interventions involved eating either the control or the wheat bran cereal three days prior to each of their visits and keeping a food diary. The results showed that the wheat bran intervention caused a significant decrease in CTT and WGTT, in which they observed a mean difference of -10.8 (p -value = 0.006) and -8.9 (p -value = 0.02), respectively. The GET and SBTT were not significantly different between the two interventions. The WMC was therefore able to detect differences in GI motility related to dietary interventions and thus demonstrated its potential for use in future digestive studies.

Appetite

Willis and colleagues designed a randomized crossover study to evaluate the utility of the WMC in research involving GI transit times and also to determine if GET had any relation to appetite.⁷ The trial compared GET, as measured by the WMC, to appetite, as determined by visual analog scales (VAS) after two different types of meals. These meals were of equivalent caloric and dietary fiber content, but one was a liquid meal and the other a solid meal.

Fourteen women were randomized according to which intervention they would receive first: the liquid breakfast consisting of fruit juice and skim milk or the solid breakfast of oatmeal, blueberries and apples.⁷ The GET was longer with the solid breakfast than the liquid breakfast: 4.2 ± 0.2 hours versus 3.3 ± 0.2 hours, respectively ($p = 0.003$). Analysis of appetite using VAS showed that patients were less hungry and more satisfied after the solid meal. Thus, there was a negative correlation between GET and appetite. The study concluded that WMC was a reasonable option for assessing GET in a nutrition or appetite study, particularly because the free mobility of the patient using WMC was as "true-to-life" as possible. One of the limitations of the WMC is the fact that the capsule is large and nondigestible, so it does not empty from the stomach until after the smaller, particulate food matter.

Critically Ill Trauma Patients

It is widely known that critically ill patients have difficulty with gastric emptying due to insufficient nutrition and delayed digestive function.²² However, monitoring the GI malfunction of these patients is difficult when they are mechanically ventilated. Furthermore, monitoring the small bowel is especially difficult due to its length, location and twisted shape. The WMC has been introduced as an alternative and innovative technique to assess GI motility in critical care patients. The study by Rauch and colleagues compared GET, SBTT and WGTT in eight critically ill trauma patients with 87 healthy volunteers from different trials using the WMC. This prospective cohort study demonstrated that the GET and the SBTT were significantly delayed for the critically ill patients group. Also, the trauma patients required 10 days to process the capsules, as compared to 1.2 days with the control group.

The results correlate with other studies that measure delayed gastric empty time with other techniques such as scintigraphy, C-octanoic acid breath test and antroduodenal manometry.²² The WMC demonstrated its ability to become an alternative method to other invasive techniques to monitor critically ill patients' gastric function, including the small intestine, where traditional technology cannot detect well.

Cystic Fibrosis

Regulating specific pH ranges in the GI tract is important to digest foods and protect from ingested microorganisms.²³ Patients with cystic fibrosis (CF) are characterized by a mutation in the cystic fibrosis transmembrane conductance regulator protein (CFTR) in the pancreas and other organs. This leads to insufficient neutralization of the gastric acid in the duodenum, causing inadequate nutrient absorption and failure to activate enteric-coated pancreatic enzyme replacement therapy (PERT) for patients with pancreatic insufficiency (PI). An antimony sensor in a swallowed pill device was used in some older studies to show that CF patients experience a more acidic small intestine relative to controls. This device is no longer used due to its instability, and a recent study by Gelfond and colleagues utilized the WMC to evaluate its potential uses to provide a distinct pH profile in CF patients. The study found that there was a statistically significant difference between mean pH values during the first 23 minutes of small bowel transit. Cystic fibrosis patients have shown a prolonged time interval to reach and maintain pH 5.5 and pH 6.0, which are pH ranges crucial for PERT dissolution. Accordingly, CF patients experienced an inadequate neutralization of gastric acid in the duodenum. Moreover, patients with CF took significantly longer time in the SBTT, while GET, CTT and WGTT were not significantly different between the two groups.

This study demonstrated the ability of the technology in the WMC to provide the distinct gastrointestinal pH profile in CF patients, which may give a valuable understanding in optimizing nutritional and pharmacological interventions in the future.²³ For instance, the research excluded CF patients without acid suppression, but there are some studies that have shown that inhibiting gastric acid may have an effect on respiratory disease by eliminating bacterial properties of

gastric acid, and the WMC can be applied to examine the effects of acid suppression in patients with CF. Furthermore, the WMC can be a useful tool to evaluate new classes of CFTR modulating drugs as well as a pharmacological intervention tool for CF patients to individualize treatments according to their gastrointestinal pH profile.

Potential Future Uses

Gastroesophageal Reflux Disease (GERD)

Although the WMC is not currently approved to diagnose GERD, it is well-equipped to measure gastric acid output (GAO), which is often a key component of GERD and other gastric hypersecretory diseases.²⁰ Weinstein and colleagues evaluated the use of the WMC as a noninvasive alternative to measuring GAO compared to a nasogastric tube. They found the WMC was an accurate and viable method of measuring GAO in healthy patients, and therefore had potential for use in research and management of disorders involving gastric acid secretion such as GERD, Barrett's esophagus, Zollinger-Ellison syndrome and atrophic gastritis. They also thought it might be applicable to antisecretory drug development and gastric cancer screening.

The WMC and nasogastric tubing were both used to determine the GAO in 20 healthy subjects.²⁰ Additionally, 12 of the subjects were later given a second WMC to test reproducibility. The statistical analysis predetermined a range (r) of 0.5 to 0.7 to be considered an acceptable correlation. Results showed a strong correlation between GAO as measured by the WMC, compared to conventional measurements, such as basal acid output (BAO) ($r = 0.51$, p -value = 0.02), maximal acid output (MAO) ($r = 0.72$, p -value = 0.0004) and peak acid output (PAO) ($r = 0.60$, p -value = 0.006). The only limitations of this study were the small sample size and the rapid GET in some patients causing an overestimation of GAO.

Patient Counseling

Pharmacists should counsel patients on important points about the function and use of the WMC. Additionally, pharmacists should warn patients to check with their physician about medications they are using that might hinder accurate test results or disease states in which WMC might be contraindicated.² Medications that might affect the procedure include pain medications, sedatives, tranquilizers, antispasmodics, promotility agents and even medications taken for heart disease, hypertension or diabetes. Pharmacists should advise the patient to complete a medication history review with their physician prior to undertaking the test. The main condition in which the use of WMC is not recommended is in patients with GI obstruction. Severe obesity may also interfere with data collection and may not be effective for these patients. The WMC procedure should not be used in patients under age 18 years.

It is important to advise patients and physicians about the cost of the WMC procedure. A capsule alone costs \$600 and the startup cost for the entire system is more.¹⁰ As of 2013, the WMC was assigned a reimbursement Category 1 CPT code (91112), stating that the 2013 National Average Medicare Physician Fee was set at \$1,188.93.²⁴ This means that

Medicare and some other insurance companies will cover the physician's fee for the procedure, but the patient will likely still have to pay for the cost of the equipment. If cost is likely to be a barrier for the patient, the WMC may not be the best option.

Conclusion

The WMC has proven to be as effective as other GI monitoring methods such as scintigraphy, antroduodenal manometry and ROM for diagnosis of gastroparesis and chronic constipation as well as a variety of research purposes. It also seems to have the potential for monitoring and management of hypersecretory conditions such as GERD. Both the advantages and limitations of the WMC in comparison to other methods need to be taken into consideration when deciding the best course of action for the patient. However, the WMC seems to be a valid option in many situations.

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