Review Article

Executing and facilitating the successful combined multichannel intraluminal impedance and pH monitoring study

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Abstract: Successful multichannel intraluminal impedance and pH monitoring (MII-pHM) studies rely on constant attendants (CAs) or family members (and sometimes the patients themselves) to assist in the execution and facilitation of the MII-pHM study. While "pushing buttons" [corresponding to specific symptoms, body position (upright versus recumbent), and meal start and stop times] on the MII-pHM system recording box is indeed a big part of MII-pHM study execution and facilitation, there are other concerns and duties that are equally as important. This paper outlines some of the important duties of the study facilitator (or patient) during a MII-pHM study. When provided with the proper training, study facilitators invigilating the MII-pHM study will be better able to contribute to the data collection process and ultimately to produce data that when analyzed will lead to better interpretations, clinical recommendations, and good clinical outcomes. When executed properly, MII-pHM studies have the potential to assess diurnal exposure of the esophageal mucosa to gastric/duodenal contents, provide insight regarding the proximal extent of gastroesophageal reflux (GER), provide a measurement of the mean esophageal pH, and assess mucosal integrity and temporal relationship between GER and the symptoms of interest. While several groups have offered recommendations for proper execution of the MII-pHM study, to our knowledge, there have not been publications wherein recommendations were compiled to form a single source document.

Keywords: Multichannel intraluminal impedance (MII); constant attendant (CA); recommendations; study facilitator

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Introduction

When a clinician decides that a combined multichannel intraluminal impedance and pH monitoring (MII-pHM) study is necessary for the assessment of gastroesophageal reflux (GER), he or she will decide whether an ambulatory study or an inpatient study is appropriate. Regardless the platform, the clinician evaluating the study relies upon the eyes and ears of others to monitor and facilitate execution of the study.

During ambulatory studies with adult or older children (1),

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Table 1 List of study facilitator responsibilities

Record the start and stop times of meals (written and electronic)
Encourage compliance
Document body positioning
Document symptoms
Constant vigilance
Monitor the position of the impedance-pH catheter
Symptoms occurring only on the day of the study
CPAP use monitoring
Using the time displayed on the recording box
Recording symptoms that may occur often or may persist
Monitoring recorder attachment to catheter
Errors should be documented

CPAP, continuous positive airway pressure.

the patient is expected to record the start and stop times of meals (using the buttons on the recorder box and maintain a written diary) and to push buttons on the recorder box corresponding to body position (upright versus recumbent) and symptoms. During ambulatory studies with younger children or older patients who require supervision (for example, special needs patients), a parent, guardian, or family member (i.e., a study facilitator) must perform these tasks. During an inpatient study, a designated constant attendant (CA) is tasked with performing these duties. Inpatient MII-pHM studies are generally required when: (I) symptoms during sleep are suspected and need to be documented; (II) a young child is being studied and the parents/caregivers have special needs and are thus incapable of performing the above-mentioned tasks; (III) the patient is at high risk of dislocating the catheter [e.g., restless leg syndrome, autism, attention deficit hyperactivity disorder (ADHD), developmental delays, etc.]; or (IV) proper supervision of a young child undergoing MII-pHM testing may not be possible because the parents/caregivers are over-burdened by the needs of other siblings in the household.

CA, in the clinical setting, is the term used to describe a hospital-affiliated individual, usually a patient care associate, or a patient services assistant, whose job is to pay close attention to a patient undergoing some type of clinical treatment or testing. During an inpatient study, in hospitals wherein adequate staffing is available, a series of CAs (ideally chosen with the special needs of the patient in mind), usually one for each of three 8-hour shifts, takes on the observation duties of the study facilitator or patient.

Preparing the study facilitator or patient

The motility team at our facility periodically provides MII-pHM training (2) sessions and then this information is communicated and clarified by motility nurses who meet with study facilitators and patients to provide a "run through" of the study and a list of the expectations (*Table 1*).

It is absolutely critical that study facilitators or patients know how to identify the symptoms of interest; for example, choking should not be misidentified as coughing.

At our facility, for every MII-pHM study, a pre-made study folder is loaded with forms that will be used to generate the handwritten diary (2): (I) an "Impedance Diet Log" and (II) an "Impedance-pHM Flow Sheet" (Appendix 1 and Appendix 2, respectively). The purpose of these unvalidated forms are explained in the text that follow.

Expectations of the study facilitator or patient during a MII-pHM study

The following recommendations will help to improve the accuracy of the data generated during the MII-pHM study; accurate data will lead to a more clinically effective study report.

Record the start time and stop time of meals

It is important that the meal button be pushed before the patient takes the first bite of food or drink of a beverage and shortly after the patient has completed the final swallow (3). Documentation should take place on the recorder box and be handwritten in the impedance diet log (Appendix 1) (4,5). The contents of the meal should also be documented (6).

Encourage compliance

The study facilitator should insist that the patient follow the feeding instructions and if the patient does not comply, the start time and stop time of the noncompliance (5) should be documented so that if esophageal acidification occurs during noncompliance, for example, the analyst will know to ignore this portion of the tracing.

Patients are prohibited from consuming acidic beverages (sodas, fruit and vegetable juices, popsicles, coffee, sports

drinks, and flavored waters) (2,3) as these beverages acidify the esophagus (perhaps for extended periods of time) and can spuriously elevate the acid reflux index. Because of the influence that temperature has on the sensitivity of the pH sensor, patients are asked to avoid extreme hot and cold foods and beverages (7). Patients are asked to refrain from snacks between meals and to limit water consumption to small periodic sips or ice chips. Patients are discouraged from grazing during meals and are thus limited to 30 minutes per meal (3). The study facilitator should encourage patients to eat at least two but preferably three meals during the study with a minimum of 3 hours between meals (8). Study patients should also be encouraged to avoid chewing gum (3) and using straws (9). For infants, pacifier use should be limited; when in use, the study facilitator should record the start and stop times in the handwritten diary.

Document body positioning

It is important that the study facilitator or patient press the "recumbent" button when the patient is lying down (2,10) with the head on the same plane at the hips. The button should only be pushed when the patient is lying completely reclined as any elevation of the chest may influence clearance of reflux due to gravity (11,12). The clinician may also request that "left side or right side" or "on back or on belly" be recorded while the patient is reclined.

Record symptoms

During a MII-pHM study, the physician requests that certain symptoms be tracked (2,3,10). The most critical symptoms are programmed into the recorder box, demarcated by a particular button, of which there are three. The study facilitator or patient presses the appropriate button whenever a symptom of interest occurs. Occasionally the physician wants to track more than three symptoms, so the study facilitator or patient needs to record the start time of the additional symptom in the handwritten diary (2) using the time marked on the recorder box (10).

The study facilitator or patient should be made abundantly sensitive to the importance of timely recording of any event that the clinician wishes to test temporal correlation with GER. If the study facilitator or patient witnesses a symptom that is programmed into the box but does not push the appropriate button in a timely fashion, he or she should document it in the written diary (Appendix 2) and not enter it into the box. Timing is important.

Constant vigilance

The inpatient option (when available) is chosen for patients who require 24-hour attention during MII-pHM testing. It is important that the CA be constantly vigilant throughout the study. Over the 24-hour study, there can be multiple CAs. It is particularly challenging for the CA working the evening shift when the lights are dimmed. The requirement (at our facility) to record the pH every 30 minutes helps the CA to remain alert.

The recording of all relevant data is one of the most important concerns for the successful execution of the MII-pHM study (2). The ability to capture all relevant symptoms throughout a 24-hour study relies on humans (or time-system-linked cameras). Without this component, nighttime symptoms go undocumented. This fact is what can distinguish the inpatient study from the ambulatory study, which incidentally is the industry standard (10,13). During a hybrid study (involving both MII-pHM and sleep monitoring), the patient sleeps 6 to 8 hours in a supervised sleep-lab, and then returns to the patient's room.

Occasionally, there are young patients who are hyperactive and present with flailing arms and legs. We see this in the patients who present with a variety of issues (e.g., autism, restless leg syndrome, developmental delays, etc.) and often in healthy infants who are simply restless. Infants should be wrapped in a blanket (14,15) and arm immobilizers or restraint mittens may be used for older infants and younger toddlers. The short length of most MII-pHM catheters is such that the recorder box is located near the patient's body and so it is important for the study facilitator to keep a watchful eye so that the patient does not accidentally push one or more of the buttons. If this happens, the study facilitator or patient (if possible) should document it in the handwritten diary (Appendix 2) so that the analyst can delete the event from the electronic diary. The recorder box is light weight so that it can hang over the side of the mattress and be out of harm's way without pulling free from the catheter cables. The study facilitator should discourage/distract young patients from holding the box.

The recorder box should never get wet so the study facilitator may need to remind the patient that he or she cannot shower until after the study has ended.

Monitor the positioning of the impedance-pH catheter

When the MII-pHM catheter is positioned within the esophagus, confirmed by X-ray (or fluoroscopy) and secured with tape to the face, the motility nurses at some facilities uses a black permanent marker pen to mark the catheter at the site where the catheter precisely enters the nostril. A significant role of the study facilitator or patient is to monitor the positioning of the catheter and alert clinical personnel if the catheter position changes (2,10).

Symptoms occurring only on the day of the study

It is important that the study facilitator or patient track only those symptoms that the patient has been experiencing before the study (2). Some symptoms, particularly atypical symptoms (16) (e.g., sneezing, nausea, hoarseness, throat clearing, etc.) occurring on the day of the study, are likely caused by the study itself and the presence of the catheter within the esophagus.

Continuous positive airway pressure (CPAP)

CPAP use has been associated with increased air swallowing (17) and subsequent GERD-like symptoms (18). CPAP has also been reported to improve symptoms of GER in some patients (19-21). For patients using a CPAP, the study facilitator or patient should document the start time and stop times for CPAP use so the MII-pHM study analyst can assess the impedance data with that in mind.

Using the time displayed on the recorder box

When documenting events in the handwritten diary, the study facilitator or patient must use the time displayed on the front of the box (2,8,10) so that when the analyst enters events into the digital diary, the synchronization permits assessment of the temporal relationship with GER.

Recording symptoms that may occur often or persist

When a patient has a coughing episode, the result may be multiple "barks" within a short time frame. However, the button should only be pressed once to indicate the first bark in the series. The same is true for symptoms like abdominal pain; when a patient complains of abdominal pain or when the study facilitator or patient notices symptoms suggestive of abdominal pain, the button should only be pressed once, even though the pain may persist. Recording the duration (approximate start and stop time) of the pain on the Impedance-pHM Flow Sheet (Appendix 2) is preferred.

Monitoring recorder box attachment to catheter lead(s)

Monitoring attachment of the catheter to the recorder box is a very important function of the study facilitator or patient during the study. If the catheter lead(s) (there may be two) pull out of the recorder box (signal loss) and does not get re-inserted in a timely manner, the study duration may become insufficient; studies of at least 14–16 hours of data (22,23) are recommended.

Errors should be documented

Errors of any type should be documented to help the analyst with his or her interpretation of the events that occurred during the study. For example, if a symptom button is pushed by accident or if the meal start button was pressed after the patient started to eat, notes should be entered into the written diary.

Discussion and conclusions

The MII-pHM technology is an extremely valuable tool for the gastrointestinal (GI) motility team. If executed properly, MII-pHM studies:

(I) Have the potential to assess diurnal exposure (bolus contact time) of the esophageal mucosa to gastric contents (acid, pepsin, bile salts, and pancreatic enzymes) (24,25);
(II) Provide insight regarding the proximal extent of GER and thus the potential for aspiration;
(III) Provide a measurement for the mean esophageal pH and, when using dual pH-sensor catheters (pediatric and adult), the gastric pH;
(IV) Assess the mucosal integrity by providing a measurement of the mean proximal and distal baseline impedance;
(V) Provide an assessment of the temporal relationship between GER (acid and nonacid) and symptoms of interest.

However, for this test to reach full potential, it must be executed properly; clinicians need documentation of all clinically relevant information in order to accurately interpret the results of the study. Study facilitators and occasionally the patients themselves are a fundamental

part of the success of these studies. The benefit of using a dedicated CA during an inpatient study is that the clinician receives a complete 24-hour picture of not only the GER, but also the symptoms and behaviors of the patient over the course of the entire study. The challenge of the ambulatory option is that a comprehensive accounting of the symptoms, particularly during sleep, may be questionable in the absence of a dedicated CA.

Day-to-day variability of MII-pHM studies has been reported (26,27). It is possible that this variability may be due to variability in study execution. Our goal is to distribute this document widely so that study facilitators and patients can be reminded of the important role they play for achieving good clinical outcomes. We invite other users of MII-pHM to use it as well.

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Footnote

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Ethical Statement: The authors are accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

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