

Evaluation of the Accuracy of Computer Automated Analysis of Esophageal 24-hour Impedance pH Studies

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Abstract

Background: Esophageal pH monitoring in conjunction with multichannel intraluminal impedance (MII-pH) is now considered the most accurate method for detection and characterization of gastro-esophageal reflux (GER), with higher sensitivity and specificity in detecting reflux than esophageal pH monitoring alone.

Aims: One possibly limiting factor for using MII-pH testing is the time required to analyze the results. Automatic interpretation softwares have been produced to reduce this, in this study, we assessed the reliability of two 24 hour MII-pH analysis softwares compared to the interpretation provided by an expert.

Methods: We performed a retrospective review of 200 MII-pH studies done on patients with reflux symptoms between September 2009 and September 2014. The studies were split into two groups of 100 patients: one group's testing was performed using MMS equipment and software, and the other group used Sandhill Scientific equipment and software. All tracings were additionally analyzed by an expert and the interpretations were compared.

Results: Our data indicated a strong correlation between the expert's analysis and both automatic softwares in all positions, Demeester score, reflux episodes and symptoms index ($p < 0.0001$). For studies interpreted as either normal or abnormal, there was concordance between the expert analysis and the software 95% of the time for the MMS software, and 93% of the instances for the Sandhill software.

Conclusions: The MII-pH data analysis software provide reliable diagnostic utility and are time-efficient at the present time, but it is advisable to seek interpretation from an experienced interpreting physician, prior to signing off the report in order to avert any possible troubles such as probe malfunctioning.

Keywords: Gastroesophageal Manometry; Electric impedance Esophageal pH monitoring

Background

Esophageal pH monitoring in conjunction with Multichannel Intraluminal Impedance (MII-pH) is now considered the most accurate method for detection and characterization of gastro-esophageal (GER).

Compared to esophageal pH monitoring MII-pH increases the sensitivity and the in detecting episodes [1]. Additionally, it patients with symptoms related to non-acid which is not detected by standard conventional pH monitoring [2,3].

Porto consensus concluded that MII-pH monitoring is the only recording method that can achieve high sensitivity for detection of all types of episodes [4]. MII-pH catheter contains six impedance segments placed at distances above the lower esophageal sphincter (LES). allow the detection of

Material and Methods

esophageal pH above 7.0. Data from previous MII-pH studies has demonstrated that non-acid reflux accounts for at least half of episodes, and bears a strong correlation with symptoms. Capabilities of MII-pH testing have been recognized, with many studies comparing the results with pH monitoring exclusively, especially for evaluation of the temporal connection between GER and symptoms [11-14].

Some previously considered drawbacks of MII-pH testing have been both the time required for an expert to analyze and interpret individual tests, and variation among expert's analysis. Because intra or inter-observer variability remain relatively high, even among experienced experts, a validated and polished automated analysis is needed for this clinical procedure. Automation ensures both reliability and reproducibility and decreases the time needed for analysis [15].

Previous research has indicated that automatic MII-pH interpretation presents problems in recognizing GER at meals, hence meals are frequently not considered in study designs. In order to thoroughly examine the accuracy in recognizing GER at meals, more work needs to be performed closely inspecting the data that is generated before, during and after meal times. We still need to make sure to exclude meals prior to automated analysis. Symptom association plotting could provide an additional tool in analyzing this association around meal periods, especially by studying the number of symptoms, the types of GER associated with symptoms, symptoms that occur in the absence of GER, and GER events that occur in the absence of symptoms [10]. A thorough analysis of this potential data may elucidate these relationships more clearly.

There have been a few noteworthy factors that may affect impedance data such as the type gathered in this study. Baseline impedance has been shown to be more reduced in patients having esophagitis, as compared to patients experiencing non-erosive disease. Additionally, proton pump inhibitor treatment outcomes have been shown to correlate with increased baseline impedance; however, this baseline impedance is also dependent on the patient's age, as well as the number of impedance events [16,17].

Our data of our study indicate that the automatic MII-pH analysis programs can provide a quick and valid method of interpreting results, with consistency and high reproducibility. Our data indicates that both the MMS and Sandhill equipment and software provide statistically similar interpretations. Furthermore, our data shows that both of the automated data interpretation bear strong correlations compared to an expert's interpretation.

Having a valid, consistent, reproducible and accurate interpretation method for MII-pH analysis enables more frequent and broader applications of this technique. Our data from this study supports the clinical strength of MII-pH analysis, and increases the potential clinical utility of this tool. Using this automated interpretation, MII-pH analysis can be more widely employed to provide important information in assessing GER, especially in the postprandial period and in patients with atypical or persistent symptoms [18]. It is prudent, of course, to have an expert interpreter quickly analyze the automated interpretation. The process should be similar to how an ECG machine's results are quickly analyzed, and, if necessary, edited by a cardiologist. The promising results of this study indicate that MII-pH analysis, with the use of these valid and quick automated programs may be a time and cost effective clinical tool. However, it is still very important that the physician responsible for the

interpretation of the pH tracings is fully trained. Accuracy is key as there are frequent issues that still need a human input, such as identifying dysfunction in the catheter which sometimes requires exclusion of sections of the tracing from analysis. This is particularly true during the overnight period where we sometimes see an inappropriate drop in pH to below 4 without associated symptoms. This is frequently due to drying of the pH electrode. If not excluded, it could erroneously elevate recumbent acid exposure time. Also, in cases of reflux the automated analysis frequently interprets multiple consecutive episodes as only one episode, thus decreasing the total number of reflux episodes. Another possible pitfall is in patients with achalasia in whom an MII-pH study is ordered, as sometimes their symptoms mimic reflux. In these cases, the baseline impedance is very low due to retained food within the esophagus. Swallows in these patients can induce waves in the retained food that can mimic reflux on the impedance tracings. An experienced physician needs to be experienced enough to identify this particular presentation and to recommend a manometry study, if not previously performed.

Ultimately, we feel that the current generations of automated MII-pH analysis programs are advanced enough to provide guidance and help shorten the length of time needed to analyze and interpret these tracings. Automation also should help provide consistency in interpretation. However, we discourage the total reliance on the automated results as this would increase the risk of erroneous results.

