

COMPUTER AUTOMATED ANALYSIS OF ESOPHAGEAL 24-HOUR IMPEDANCE PH STUDIES

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ABSTRACT

Aim: was to evaluate the reliability of two different types of 24 hour MII-pH analysis softwares compared to the interpretation provided by an expert was assessed. **Material and method:** The present study was conducted in the department of physiology at BJS Dental College, Ludhiana with the help of gastro surgery department of SPS hospital, Ludhiana. A retrospective review of 100 consecutive MII-Ph studies was done on adult patients with typical or atypical reflux symptoms referred to laboratory for MII-pH monitoring. The studies were split into two groups of 50 patients each: One group had testing performed using MMS equipment, and the other group using Sandhill scientific equipment. The symptoms associated are calculated using three different indices: symptom sensitivity index (SSI), symptom index (SI), and symptom association probability (SAP). Data were tabulated and examined using the Statistical Package for Social Sciences Version 20.0 (IBM SPSS Statistics for Mac, Armonk, NY: IBM Corp, USA). **Results:** The results showed a very strong correlation between the expert's analysis and both automatic softwares as shown for the upright position, supine position, Demeester score, acid and non-acid reflux episodes as well as symptoms index. **Conclusion:** The current study indicates strong correlations between the interpretations provided by the automatic software analysis and an expert analysis for 24 hour MII-pH monitoring, and are significantly less time consuming.

KEYWORDS: Gastroesophageal reflux; Esophageal pH monitoring; Manometry; Electric impedance.

INTRODUCTION

MII-pH significantly increases the sensitivity and the specificity in detecting reflux episodes.^[1] Additionally, it identifies patients with symptoms related to non-acid reflux, which is not detected by standard conventional pH monitoring.^[2] Esophageal pH monitoring in conjunction with Multichannel Intraluminal Impedance (MII-pH) is now considered the most accurate method for detection and characterization of gastroesophageal reflux (GER).

Measurements of MII-pH monitoring have been shown in a prospective study to detect GERD with higher levels of specificity and positive predictive values than wireless pH monitoring.^[3] The FDA has approved use of MII-pH to monitor reflux by detecting retrograde intraluminal bolus movement. As a result, patients with normal endoscopic findings on acid suppression therapy with persistent GERD symptoms have an indication to undergo MII-pH monitoring to quantify reflux episodes, classify the type of reflux (i.e. acidic vs. nonacidic), and

assess the relationship between persistent symptoms and MII-detected reflux.^[4] In the present study, reliability of two different types of 24 hour MII-pH analysis softwares compared to the interpretation provided by an expert was assessed.

MATERIALS AND METHOD

The present study was conducted in the department of physiology at BJS Dental College, Ludhiana with the help of gastro surgery department of SPS hospital, Ludhiana. A retrospective review of 100 consecutive MII-Ph studies was done on adult patients with typical or atypical reflux symptoms referred to laboratory for MII-pH monitoring. Patients with dysphagia and history of gastric surgery were excluded because of the potential for esophageal dysmotility. Meal times were excluded from analysis. The study was approved by the Institutional Review Board of the college.

The studies were split into two groups of 50 patients each: One group had testing performed using MMS

equipment, and the other group using Sandhill scientific equipment. We performed the analysis using the corresponding software for each device: MMS version V8.19h and Bioview analysis (Sandhill scientific) version 5.5.4.1, respectively. All patients were asked to fast for at least 4-6 hours before the procedure while still taking their usual medications, including acid suppression therapy. The catheter design placed the pH electrode 5 cm above and 10 cm below the lower esophageal sphincter (LES) with impedance measuring segments at 3 cm, 5 cm, 7 cm, 9 cm, 15 cm, and 17 cm above the LES.

All patients were provided with a diary to mark the time and content of meals, time and type of symptoms, time and type of medications, and recumbent and upright positions during the study period. Symptoms and patient position were also recorded by pressing assigned buttons on the MII-pH monitor. The following day, the catheter was removed and data were downloaded for analysis. A reflux episode was defined by cephalad bolus movement as seen on MII. It was regarded as acid reflux if pH dropped below 4 and non-acid reflux if pH remained at 4 or above.

The total number of reflux episodes in patients on acid-suppression therapy had a threshold for abnormal reflux at 48 reflux episodes in 24 hours, an average of approximately two reflux episodes per hour. All tracings were interpreted by the same expert with an experience of having read more than 2,000 MII-pH studies. For the purpose of this study, a trainee with no prior experience in interpreting MII-pH tracings collected the data from the expert analysis and then reset the tracings to their original status prior to modification by the expert, and applied automated analysis using the newer versions of the software. The trainee subsequently also collected the reflux data generated by the automated analysis. The basic concepts of esophageal impedance are similar to pH monitoring; whereby the esophageal data are documented via a probe positioned transnasally with the help of a recorder. Upon completion of data acquisition, the raw data are then downloaded into specific software, the MMS version V 8.19h and the Bioview analysis (Sandhill scientific) version 5.5.4.1, that prepares a tracing and is capable of automatic analysis. The symptoms associated are calculated using three different indices: symptom sensitivity index (SSI), symptom index (SI), and symptom association probability (SAP)^[5]

Statistical analysis

Data were tabulated and examined using the Statistical Package for Social Sciences Version 20.0 (IBM SPSS Statistics for Mac, Armonk, NY: IBM Corp, USA). Pearson correlation test was used to test the relation between MMS and Sandhill. A p-value <0.05 was considered significant.

RESULTS

Total 50 studies were done using MMS equipment and software (MMS version V 8.19h) and 50 studies were done using Sandhill scientific equipment and software (Bio view analysis version 5.5.4.1). As shown in table 1, data indicated a very strong correlation between the expert’s analysis and both automatic softwares as shown for the upright position, supine position, Demeester score, acid and non-acid reflux episodes as well as symptoms index.

Table 1: Correlation between the interpretation of the expert and the automatic software.

Variables	MMS		Sandhill	
	r value	p value	r value	p value
Demeester score	0.94	<0.01*	0.95	<0.01*
Upright% time ph<4	0.98	<0.01*	0.97	<0.01*
Supine% time ph<4	0.93	<0.01*	0.93	<0.01*
Acid reflux episodes	0.91	<0.01*	0.90	<0.01*
Non acid reflux episodes	0.89	<0.01*	0.86	<0.01*
Symptom index	0.85	<0.01*	0.76	<0.01*

*: statistically significant

DISCUSSION

Data from previous MII-pH studies has demonstrated that non-acid reflux accounts for at least half of reflux episodes, and bears a strong correlation with symptoms. The 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] 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 interobserver variability remain relatively high, even among experienced experts, a validated and polished automated analysis is needed for this clinical procedure. This ensures both reliability and reproducibility and significantly decreases the time needed for analysis.^[6]

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

The data from the present study supports the clinical strength of MII-pH software analysis, and increases the potential clinical significance of this tool. Using this

software interpretation, MII-pH analysis can be more confidently employed to provide important information in assessing GER, especially in the postprandial period and in patients with atypical or persistent symptoms.^[7] It is prudent, of course, to have an expert interpreter quickly analyze the software's interpretation. This 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 software programs may be a time and cost efficient clinical tool. However, it is still very important that the physician responsible for the interpretation of the pH tracings is fully trained. This 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 reflux. This is frequently due to drying of the pH electrode. If not excluded, it could erroneously elevate recumbent acid exposure time.

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

Limitations of our study include Single center sample, and the inability to study all available impedance pH softwares as well as the inability to get multiple expert's readings for the same impedance pH study to compare it with different types of softwares.

CONCLUSION

The current study indicates strong correlations between the interpretations provided by the automatic software analysis and an expert analysis for 24 hour MII-pH monitoring, and are significantly less time consuming. The two software, MMS and Bioview, are very reliable 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.

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