

# SEVERITY OF REFLUX PREDICTS NUMBER OF DAYS ABNORMAL ON AMBULATORY REFLUX TESTING: DISCOVERY AND EXTERNAL VALIDATION COHORT STUDY

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## INTRODUCTION

- Ambulatory reflux monitoring off PPI has become a leading option for the diagnosis of GERD.
- Even with adoption of the Lyon Consensus, there remains controversy on ambulatory reflux parameters for the prediction of abnormal reflux
- If severity of reflux on 48-hour monitoring can predict number of days abnormal, this may obviate the need for 96-hour prolonged pH monitoring.

## AIM

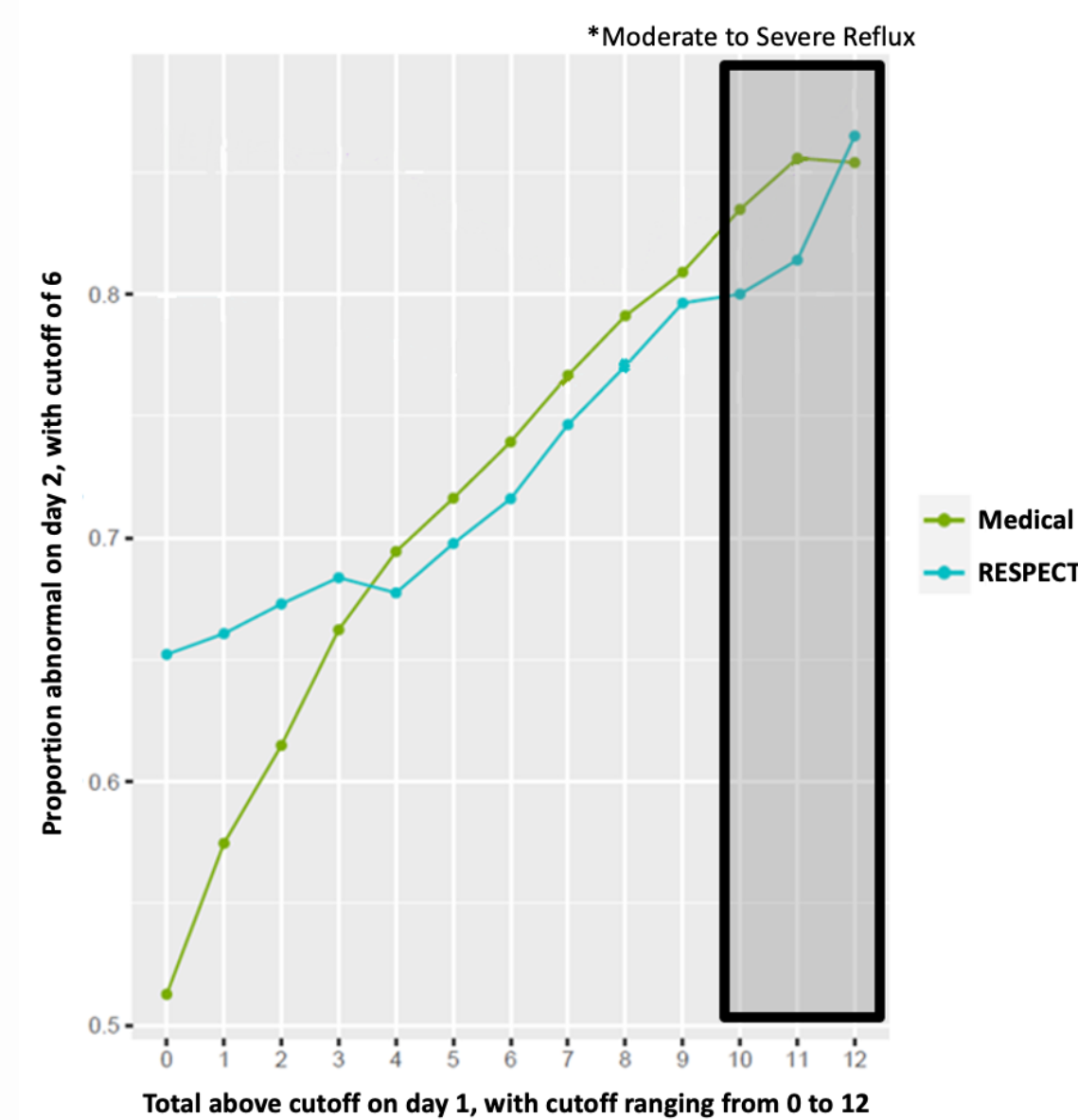
- To evaluate if severity of reflux alone predicted the number of days of abnormal acid exposure.

## METHODS

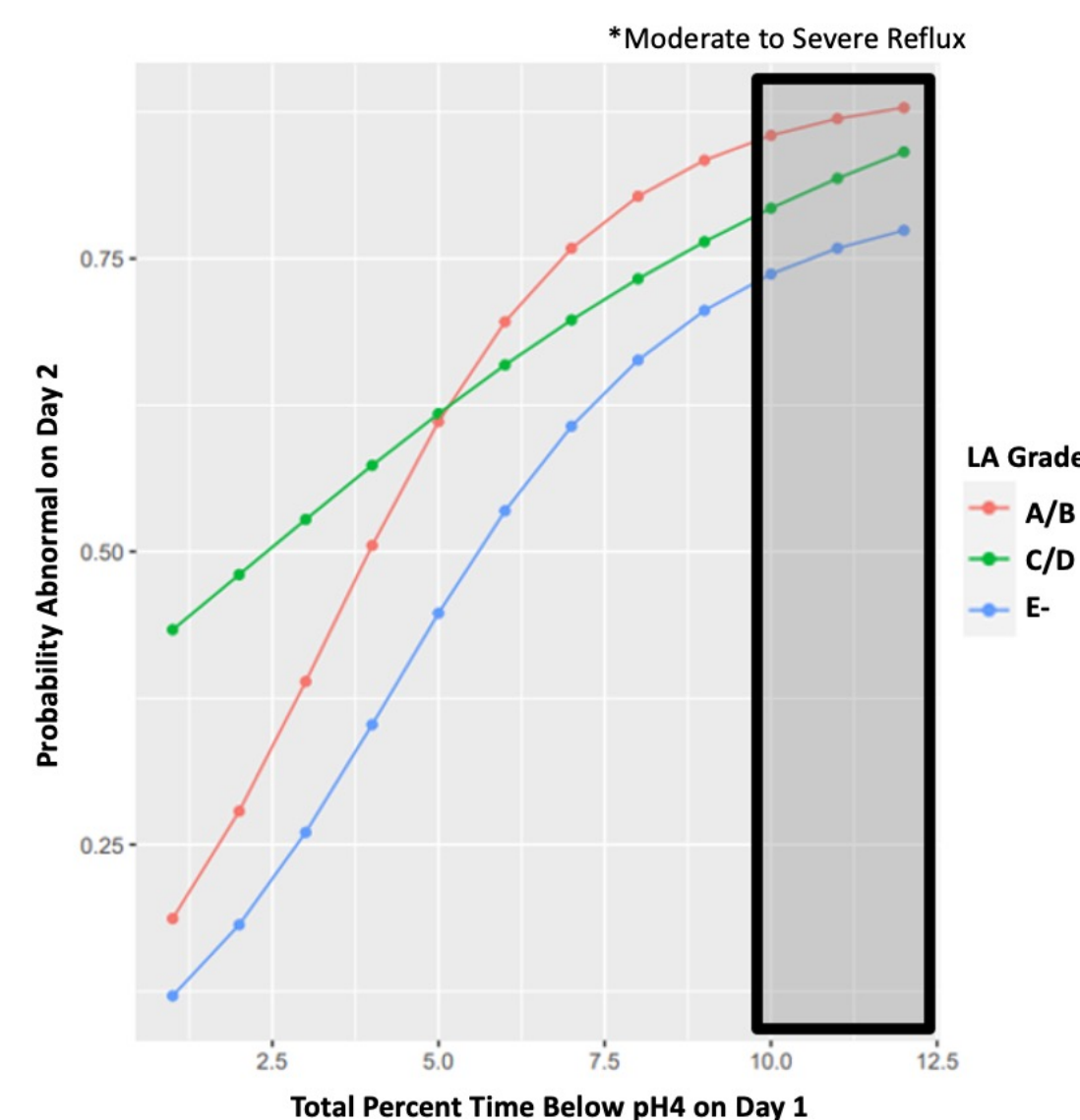
- Our discovery cohort included single center data from patients with GERD symptoms despite PPI evaluated by pH testing (“Medical”).
- The Medical group was compared to an external validation cohort from the clinical randomized control trial of TIF 2.0 (“RESPECT”) during parallel time-periods over 10 years.
- RESPECT patients had symptoms and were being evaluated to undergo TIF 2.0. 48 Hour wireless pH testing was performed at least 7 days off PPI therapy in all subjects.
- Patient with a history of prior fundoplication, gastric surgery, Barrett’s esophagus or neoplasia were excluded.
- Percent total time pH<4 was considered abnormal if greater than 6% (Lyon Classification). The probability of having abnormal reflux was measured based on severity and frequency of reflux events.
- Wilcoxon and Pearson  $\chi^2$  tests were used for comparison of continuous and categorical variables, respectively.

## RESULTS

**Figure 1: Severity of Reflux (x-axis) Compared to Proportion Abnormal Reflux Parameters on Day 1 vs Day 2 (y-axis)**



**Figure 2: Comparison of LA Grade Esophagitis by Abnormal Acid Exposure Time on Day 1 vs Day 2**



## CONCLUSIONS

- Our cohorts included the RESPECT group (n=129, 49% male) compared to Medical group (n=119, 30% male).
- Frequency of abnormal days on pH monitoring was highly dependent on severity of reflux events with a 91-93% likelihood of both days being abnormal if reflux AET was 12% or greater (Figure 1).
- Using 6.0% AET on the worst day, the prediction for the 2<sup>nd</sup> day to also be abnormal was driven by severity of reflux event (Medical= 78% at a AET of 6.0, 88% at AET of 10, and 91% at AET of 12).
- This was similar for the validation cohort (RESPECT = 72% at a AET of 6.0, 80% at AET of 10, and 93% at AET of 12) (p-value for non-linear effects <.0001) (Figure 1). This finding was consistent between the discovery and validation cohorts irrespective of esophagitis status (Figure 2).

## IMPLICATIONS

- Severity of reflux (defined by abnormal acid exposure time) is highly predictive of number of days abnormal.
- Utilizing the severity of reflux on ambulatory testing potentially obviates the need for extended ambulatory monitoring beyond 48 hours.
- As severity of reflux worsens, the predictive power for number of abnormal days is strengthened (from current Lyon of 6.0% to moderate-severe ranges of 10-12%).
- When using ambulatory reflux testing, increased focus on the severity of reflux has higher predictive power in guiding patient diagnosis.

