VALIDATION OF THE MILAN SCORE WITH PROLONGED WIRELESS PH MONITORING

BACKGROUND AND AIM
In 2024, a novel high-resolution manometry (HRM) metric termed the Milan Score (MS) was introduced to quantify anti-reflux barrier disruption and to estimate the probability of pathologic gastroesophageal reflux disease (GERD) (1). This composite score integrates four HRM parameters: ineffective esophageal motility, esophago-gastric junction (EGJ) morphology, EGJ-contractile integral (EGJ-CI) and response to the straight leg raise (SLR) maneuver. Following its introduction, the use of the MS has spread, supported by initial validation studies across diverse clinical contexts. However, its validation has relied on 24-hour pH-impedance studies, making the outcome susceptible to day-to-day variability. Aim of this study is to validate the effectiveness of the MS in predicting GERD with prolonged 96 hours wireless pH-monitoring.

MATERIALS AND METHODS
Adult patients (18-75 years) with GERD symptoms who completed an adequate HRM and wireless 96 hours pH-monitoring within 2 weeks from each other at our institution were included in the study. Patients with prior foregut surgery, hiatal hernia >5 cm, scleroderma and eosinophilic esophagitis were excluded. Demographic, clinical, endoscopic and functional variables were collected. Two groups were identified according to GERD diagnosis per Lyon 2.0 consensus and compared. Differences in terms of pH variables were assessed in patients with positive ($\geq$137) and negative (< 137) MS. The performance of the MS in predicting pathologic GERD was determined using the receiver operator characteristics (ROC) analysis.

RESULTS
Among the 56 patients included (56% males, age 52 years, BMI 23.7), 29 had GERD. Patients with GERD had higher BMI and waist circumference, and a greater frequency of hiatal hernia and esophagitis at endoscopy. Manometric hiatal hernia (p=0.001) and positive SLR maneuver (p<0.001) were significantly more frequent in the GERD group. A positive Milan Score was found in 69% of the GERD group and in 3.7% of the no-GERD group (p<0.001). Patients with positive Milan Score had higher total acid exposure time (AET) (8.7% vs. 2.4%, p<0.001), as well as supine AET (5.3% vs. 0.5%, p<0.001) and upright AET (10% vs. 3%, p<0.001), number of positive days (**FIGURE 1,** p=0.003), pathologic GERD (95% vs. 26%, p=0.001) and DeMeester score (28 vs. 9, p<0.001). ROC analysis yielded an AUC of 0.871 (95% CI: 0.774–0.968). At the previously validated threshold of 137 (GERD risk rate 50%), sensitivity was 61.1% and specificity 94.1%. In this cohort of patients, an optimal threshold of 148 was identified, with sensitivity 67.3% and specificity 98.2%.

CONCLUSIONS
This validation study using prolonged 96-hour wireless pH-monitoring strengthen existing evidence on the ability of the Milan Score to effectively predict pathologic GERD.

REFERENCES

1. Siboni S, Sozzi M, Kristo I et al. The Milan score: A novel manometric tool for a more efficient diagnosis of gastro-esophageal reflux disease. United European Gastroenterol J. 2024 Jun;12(5):552-561. doi: 10.1002/ueg2.12565. Epub 2024 Mar 27. PMID: 38536701; PMCID: PMC11176912.

Figure 1. Distribution of positive days in patients with negative and positive Milan Score