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Article:

Ford, AC orcid.org/0000-0001-6371-4359 (2018) Utility of the Oral Capsaicin Test in Diagnosing Functional Dyspepsia. *The American Journal of Gastroenterology*, 113. pp. 1257-1258. ISSN 0002-9270

<https://doi.org/10.1038/s41395-018-0113-9>

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TITLE PAGE

Title: Utility of the Oral Capsaicin Test in Diagnosing Functional Dyspepsia.

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Abbreviations: FD functional dyspepsia
GI gastrointestinal
IBS irritable bowel syndrome
LR likelihood ratio

Word count: 497

Disclosures: ACF: none to declare.

Author contributions: ACF drafted the letter and approved the final draft of the manuscript.

To the Editor;

I read the recent paper by Hammer, reporting the diagnostic utility of an oral capsaicin test in the diagnosis of functional dyspepsia (FD), with interest. (1) The author correctly points out that diagnosing functional gastrointestinal (GI) disorders is challenging, with no widely accepted biomarker for FD or irritable bowel syndrome (IBS). (2, 3) The author reported a sensitivity of 51%, specificity of 87%, and positive and negative likelihood ratios (LRs) of 4.08 and 0.56 respectively, compared with a gold-standard of a negative endoscopy and reporting symptoms compatible with the Rome III criteria for FD.

Most patients with dyspepsia without alarm symptoms, when subject to upper GI endoscopy, will have no structural abnormality identified. (4) This means that the majority of patients with dyspeptic symptoms have FD, and endoscopy would be avoided if this group could be identified accurately, and treated accordingly. However, given the performance statistics of the oral capsaicin test, its use is unlikely to prevent unnecessary endoscopy; the LRs reported in this study were only modest. A positive LR of >10 and a negative LR of <0.1 are generally considered as useful for ruling in or ruling out a disease. (5) In fact, the performance of the oral capsaicin test in predicting FD was only slightly better than that of the Rome III criteria themselves in a large Canadian study. (6) In this study, when the Rome III criteria were applied prospectively to 1452 unselected patients with upper GI symptoms undergoing endoscopy their sensitivity, specificity, and positive and negative LRs, in identifying functional dyspepsia, were reported as 61%, 69%, 1.94, and 0.57 respectively.

In addition, and for reasons that are unclear, rather than testing the performance of the oral capsaicin test in an unselected group of patients undergoing endoscopy for upper GI symptoms, the author tested its performance in a mixed group of patients with upper GI symptoms, such as dyspepsia and gastro-esophageal reflux, as well as patients with known

lower GI disorders, including IBS and inflammatory bowel disease, and a group of patients with other GI and non-GI disorders. It is unclear why these other two patient groups were included and, given that patients with lower GI and non-GI diseases are probably less likely to demonstrate a positive test, their inclusion is likely to have enhanced the modest performance of the oral capsaicin test. This is akin to spectrum bias, seen in case-control studies, where by using two extreme groups of patients the study design often omits mild cases that are more difficult to diagnose, leading to an overestimation of the diagnostic performance of the test being examined, compared with studies that use a true unselected clinical cohort. (7)

In summary, although the performance of the oral capsaicin test in this single center study recruiting a mixed group of patients with upper GI, lower GI, and non-GI disorders was encouraging, it needs to be replicated in large unselected cohorts of patients presenting for endoscopy with upper GI symptoms.

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