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SENSITIVITY, SPECIFICITY AND REPRODUCIBILITY OF THE C-14-UREA BREATH TEST: EVALUATION IN PATIENTS WITH C.PYLORI ASSOCIATED GASTRITIS. BJ Marshall, MW Plankey, RL Guerrant, RW McCallum. University of Virginia, Charlottesville Va.

Campylobacter-like organisms (CLO) may be diagnosed by histological examination of gastric mucosal biopsies, biopsy urease test and/or culture, or noninvasively by the C-14-urea breath test (BT). In this study our goal was to determine the sensitivity, specificity and reproducibility of the breath test as compared against the histological "gold standard".

After a six hour fast, sixty-nine consecutive dyspeptic patients were asked to cleanse their mouths by toothbrushing and were then given 10 uCi C-14-urea orally. Breath samples were then collected into 2 mls of 0.25 molar solution of hyamine in menthanol with a pH indicator at 0,2,15,20,25 and 30 minutes. Immediately following the BT, an upper gastrointestinal endoscopy was performed where mucosal biopsies were taken from the antrum and body and examined by Giemsa stain for CLO. Each BT sample was counted for 10 minutes and results were expressed as (% of dose administered in sample) x body weight/(mmole of CO<sub>2</sub> collected). If the area under the curve between 15 and 30 minutes was  $\geq 1.6$  units, the test was interpreted as positive. In order to measure the reproducibility of the BT, a repeat test was performed in 11 randomly selected patients within one week of initial evaluation. The summary of the results are as follows:

<u>BREATH TEST STATUS</u>	<u>BIOPSY STATUS</u>	
	CLO-	CLO+
BT-	31	3
BT+	2	33

The sensitivity and specificity of the BT were 92% and 94%, respectively. Reproducibility was measured by linear regression analysis with  $r=0.70$ . False-positive results occurred in patients with high counts in the initial 2 min sample, perhaps indicating periodontal disease or incomplete mouth cleansing. Two of 3 false-negative tests were in elderly patients with intestinal metaplasia and low numbers of organisms.

We conclude that the C-14-urea breath test is a reliable, noninvasive and well tolerated test for the diagnosis of CLO associated gastritis.