Clinical Validation of C-PDR Methodology for Accurate Non-Invasive Detection of Helicobacter pylori Infection

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Abstract : Background: Helicobacter pylori is a common and important human pathogen and the primary cause of peptic ulcer disease and gastric cancer. Currently H. pylori infection is detected by both invasive and non-invasive way but the diagnostic accuracy is not up to the mark. Aim: To set up an optimal diagnostic cut-off value of 13C-Urea Breath Test to detect H. pylori infection and evaluate a novel c-PDR methodology to overcome of inconclusive grey zone. Materials and Methods: All 83 subjects first underwent upper-gastrointestinal endoscopy followed by rapid urease test and histopathology and depending on these results; we classified 49 subjects as H. pylori positive and 34 negative. After an overnight, fast patients are taken 4 gm of citric acid in 200 ml water solution and 10 minute after ingestion of the test meal, a baseline exhaled breath sample was collected. Thereafter an oral dose of 75 mg 13C-Urea dissolved in 50 ml water was given and breath samples were collected upto 90 minute for 15 minute intervals and analysed by laser based high precisional cavity enhanced spectroscopy. Results: We studied the excretion kinetics of 13C isotope enrichment (expressed as $\delta DOB13C$ ‰) of exhaled breath samples and found maximum enrichment around 30 minute of H. pylori positive patients, it is due to the acid mediated stimulated urease enzyme activity and maximum acidification happened within 30 minute but no such significant isotopic enrichment observed for H. pylori negative individuals. Using Receiver Operating Characteristic (ROC) curve an optimal diagnostic cut-off value, $\delta DOB13C$ ‰ = 3.14 was determined at 30 minute exhibiting 89.16% accuracy. Now to overcome grey zone problem we explore percentage dose of 13C recovered per hour, i.e. 13C-PDR (%/hr) and cumulative percentage dose of 13C recovered, i.e. c-PDR (%) in exhaled breath samples for the present 13C-UBT. We further explored the diagnostic accuracy of 13C-UBT by constructing ROC curve using c-PDR (%) values and an optimal cut-off value was estimated to be c-PDR = 1.47 (%) at 60 minute, exhibiting 100 % diagnostic sensitivity , 100 % specificity and 100 % accuracy of 13C-UBT for detection of H. pylori infection. We also elucidate the gastric emptying process of present 13C-UBT for H. pylori positive patients. The maximal emptying rate found at 36 minute and half empting time of present 13C-UBT was found at 45 minute. Conclusions: The present study exhibiting the importance of c-PDR methodology to overcome of grey zone problem in 13C-UBT for accurate determination of infection without any risk of diagnostic errors and making it sufficiently robust and novel method for an accurate and fast non-invasive diagnosis of H. pylori infection for large scale screening purposes.

Keywords : 13C-Urea breath test, c-PDR methodology, grey zone, Helicobacter pylori
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