Reviewer's report

Title: A survey of functional dyspepsia using Rome III criteria among Malay subjects attending primary care clinic in an area with low prevalence for Helicobacter pylori infection

Version: 1 Date: 2 October 2012

Reviewer: Sanjiv Mahadeva

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Summary

This is a cross-sectional study of a selected group of patients of Malay ethnicity (known for their low H. pylori prevalence) attending a hospital-based primary care clinic, examining the epidemiology & clinical patterns of functional dyspepsia (FD), using a locally translated version of the Rome III G.I. questionnaire. Among 160 patients surveyed, 19 patients with positive symptoms for FD underwent an upper GI endoscopy and an eventual 16 (10%) patients had true FD. H. pylori was not detected in any of the 19 patients. Alarm or red flag symptoms were present in 6/16 (37.5%) of FD patients and epigastric pain syndrome was found to be the most common type of FD. Only a "married status" and "positive psychosocial alarm symptoms" were found to be independent predictors of FD.

The study provides some useful information among ethnic Malays, but I have some concerns:

MAJOR COMPULSORY REVISION

1. I have concerns about the calculation of the sample size. As the focus of this study was on examining the epidemiology of FD in a population with a low H. pylori prevalence, the estimated prevalence of H. pylori should be factored into the sample size calculation.

   The fact that the H. pylori prevalence among the FD sample was 0%, indicates that this sample size was too small to study any relation between FD and H. pylori (i.e. a Type II error).

2. The authors reported that they wanted to study the epidemiology of FD among patients attending a primary care clinic instead of the general population as the "risk profile" may be different to that of the general population. However, there is little discussion about the differences in epidemiology between these primary care FD patients and other population-based studies from this region and elsewhere in Asia. I suggest a paragraph or more should be dedicated to this issue in the "Discussion" section.
3. The validity of the Rome III questionnaire in diagnosing FD should be mentioned in the "Discussion" section. Whilst a formal translation of the Rome III criteria was performed, no validation of the instrument for detecting FD in this population had been conducted. Furthermore, 3/19 patients of patients diagnosed with FD (by Rome III criteria) were found to have erosive GERD. Some discussion on this issue and the accuracy of the Rome III criteria in diagnosing true FD should be made - for eg., does the Rome criteria have any significance in clinical practice, or is it more a tool for research?

4. As the study sample were patients attending a clinic, data on co-morbidity and medications consumed should have been available. Was there any relationship between FD and chronic illnesses (eg Diabetes) and between FD and analgesic/Aspirin consumption? This information can then be used to contrast with population-based data, where the study sample should theoretically more "healthy".

MINOR ESSENTIAL REVISIONS

1. 37.5% of patients with FD had Red Flag symptoms. The relevance of this finding, i.e. the limitations of alarm symptoms, should be mentioned in the "Discussion" section. Similar findings have been reported from other studies in this region & elsewhere.

2. Pg 7, 1st paragraph - the number of 160 patients should be moved to the "Results" section.

3. Pg 8, 2nd paragraph, last sentence - "Eventually 160 subjects....." - this should be mentioned in the "Results" section.

4. Endoscopy was performed by a single endoscopist blinded to the study - in what manner was blinding performed?

5. The authors mention that FD was greater among married females than married males. What was the difference between married & un-married females? If there was a difference, then this would strengthened the association of married status

Level of interest: An article of importance in its field

Quality of written English: Needs some language corrections before being published

Statistical review: No, the manuscript does not need to be seen by a statistician.

Declaration of competing interests:

I declare that I have no competing interests