

**Title** NASOMETER FOR DIAGNOSING NASALITY IN CLEFT PALATE PATIENTS

**Agency** HTA Malaysia, Health Technology Assessment Section, Medical Development Division, Ministry of Health Malaysia  
Level 4, Block E1, Parcel E, Presint 1,  
Federal Government Administrative Center, 62590 Putrajaya, Malaysia  
Tel: +603 88831229, Fax: +603 88831230; htamalaysia@moh.gov.my, www.moh.gov.my

**Reference** Technology Review Report - 017/2015, online:  
[http://www.moh.gov.my/index.php/database\\_stores/store\\_view\\_page/30/273](http://www.moh.gov.my/index.php/database_stores/store_view_page/30/273)

#### Aim

To review the available evidence on the effectiveness, safety and cost-effectiveness of nasometer in relation to assessment and diagnosing nasality in cleft palate patients.

#### Conclusions and results

Three articles related to nasometer for diagnosing nasality in cleft palate patients is included in this review: two diagnostic accuracy studies and one cross-sectional study. The studies were conducted in United Kingdom, Ireland, United States, and Malaysia. There was limited fair level of retrievable evidence to indicate that the nasometer was effective in diagnosing nasality in cleft palate patients. The relationship between the perceptual ratings and the nasometry results varied across studies, and this variability may be related to differences in design such as different instruments, stimuli, and methods of obtaining nasality judgements. Correlation analysis, test sensitivity, specificity, and overall efficiency has been used for the evaluation. The correlation coefficient (r) analysis revealed a positive relationship between perceptual ratings of nasality and nasalance scores for each sentence category as the following:

- Total test sentences:  $r=0.74$ ,  $p<0.001$
- High-pressure consonant sentences:  $r=0.74$ ,  $p<0.001$
- Low-pressure consonant sentences:  $r=0.64$ ,  $p<0.001$

Test sensitivity, specificity, and overall efficiency indicated a good relationship between perceptual judgements of hypernasality and nasalance scores for each sentence category as the following:

- Total test sentences: cut-off=35%; sensitivity=83%, specificity=78%, efficiency=82%
- High-pressure consonant sentences: cut-off=24%; sensitivity=83%, specificity=86%, efficiency=84%
- Low-pressure consonant sentences: cut-off=28%; sensitivity=88%, specificity=78%, efficiency=86%

Equal appearing interval (EAI) nasality ratings methods were comparable with direct magnitude estimation (DME) methods with regard to the relationship between nasalance and nasality. The magnitude of the correlation between nasalance scores and two nasality ratings methods was not significantly different ( $r=0.63$  and  $r=0.59$ , respectively). Nasometer test sensitivity and specificity were similar for EAI-and DME-rated nasality:

- EAI-rated nasality: sensitivity=0.71, specificity=0.73
- DME-rated nasality: sensitivity=0.62; specificity=0.70

There was no retrievable evidence on the adverse events or complications related to the use of the device, and on its cost-effectiveness. In addition, there was no retrievable evidence on the approval of the device by the United States Food and Drug Administration (US FDA).

#### Recommendations (if any)

It is recommended for research purpose or to be used in research environment

#### Methods

Electronic databases were searched, which included PubMed, Medline, Journal @ Ovid full text via OVID, OVID EBM Reviews - Cochrane central register of controlled trials, EBM Reviews - Cochrane database of systematic review, Horizon scanning databases - Centre, Birmingham, Australia and New Zealand Horizon scanning (ANZHSN), FDA website, MHRA website and from non-scientific database - Google search engine. In addition, a cross-referencing of the articles retrieved was also carried out accordingly to the topic. Relevant articles were critically appraised and evidence graded using US/Canadian Preventive Services Task Force.

#### Further research/reviews required

More research is needed to ascertain the effectiveness of nasometer in diagnosing nasality in cleft palate patients

#### Written by

Syful Azlie Md Fuzi, MaHTAS, Malaysia