NICEVIS - Results of a randomised controlled trial of simeticone and n-acetylcysteine as a pre-procedure drink to improve mucosal visibility during diagnostic gastroscopy

Pete Basford, 1 James Brown, 1 Lisa Gadeke, 1 Carole Fogg, 1 Ben Haysom-Newport, 1 Reuben Ogollah, 1 Bernie Higgins, 1 Rupam Bhattacharyya, 1 Gaius Longcroft-Wheaton, 1 Fergus Thursby-Pelham, 1 James Neale, 1 Pradeep Bhandari 1
1. Gastroenterology, Portsmouth Hospitals NHS Trust, Portsmouth, Hampshire, United Kingdom. 2. University of Portsmouth, Portsmouth, United Kingdom. 3. South Devon Healthcare NHS Trust, Torbay, United Kingdom.

Introduction & Aims
- Despite advances in endoscope technology there is still a significant miss rate of neoplastic lesions during gastroscopy. Mucosal views during gastroscopy are frequently impaired by residual bubbles and mucus.

Methods
- We conducted a randomised controlled trial in 126 patients attending for routine outpatient gastroscopy.
- Subjects were randomised in a 1:1:1 ratio to receive a pre-procedure drink of:
  - Water, Simeticone and n-acetylcysteine (Group A)
  - Water alone (Group B)
  - Water alone (Group C)
- Study endoscopists were blinded to group allocation.
- 4 digital images were taken at pre-defined locations during the procedure – lower oesophagus, upper body, antrum & fundus.
- Images were then collated and rated for mucosal visibility (MV) using a 4 point scale (1 = best, 4 = worst) by 4 separate experienced endoscopists who were also blinded to group allocation.
- The primary outcome measure was mean mucosal visibility score.
- Secondary outcome measures were total procedure duration and volume of fluid flush required during the procedure to achieve adequate mucosal views.

Results
- There were no significant differences between groups in age, gender or indication for endoscopy.
- Interobserver agreement of MV scores was good (mean kappa 0.464)
- The mean MV score for group A was significantly better than for group B and group C but there was no significant difference in mean MV score between groups B and C – see table 1
- Mean volume of flush required during gastroscopy to achieve adequate mucosal views was significantly lower in group A than group B and group C. There was no significant difference in mean flush volume between groups B & C.
- Procedure duration did not differ significantly between any groups.
- Subgroup analysis of MV scores at each location demonstrated significantly better mucosal visibility in group A compared to group B and group C at all locations.

Table 1 – Mucosal visibility scores, procedure duration and volume of flush used by study group

<table>
<thead>
<tr>
<th>Location Score (mean, 95%CI)</th>
<th>Study Group</th>
<th>A (Water/NAC/Simeticone)</th>
<th>B (Water)</th>
<th>C (No prep.)</th>
<th>P value A vs B</th>
<th>P value A vs C</th>
<th>P value B vs C</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lower Oesophagus</td>
<td></td>
<td>1.18 (1.09-1.28)</td>
<td>1.69 (1.48-1.89)</td>
<td>1.93 (1.66-2.21)</td>
<td>0.002</td>
<td>&lt;0.001</td>
<td>0.210</td>
</tr>
<tr>
<td>Upper Body</td>
<td></td>
<td>1.58 (1.39-1.77)</td>
<td>2.34 (2.11-2.57)</td>
<td>2.36 (2.10-2.62)</td>
<td>&lt;0.001</td>
<td>&lt;0.001</td>
<td>0.992</td>
</tr>
<tr>
<td>Antrum</td>
<td></td>
<td>1.20 (1.09-1.30)</td>
<td>2.31 (2.02-2.60)</td>
<td>2.40 (2.08-2.71)</td>
<td>&lt;0.001</td>
<td>&lt;0.001</td>
<td>0.869</td>
</tr>
<tr>
<td>Fundus</td>
<td></td>
<td>1.45 (1.27-1.63)</td>
<td>2.10 (1.90-2.30)</td>
<td>2.16 (1.92-2.40)</td>
<td>&lt;0.001</td>
<td>&lt;0.001</td>
<td>0.914</td>
</tr>
<tr>
<td>Total</td>
<td></td>
<td>5.40 (5.02-5.80)</td>
<td>8.44 (7.91-8.97)</td>
<td>8.85 (8.17-9.53)</td>
<td>&lt;0.001</td>
<td>&lt;0.001</td>
<td>0.541</td>
</tr>
</tbody>
</table>

Figure 1 – Mucosal visibility score examples - top left = 1, top right = 2, bottom left = 3, bottom right = 4

Figure 2 – Distribution of MV by group

Conclusions
- A pre-procedure drink containing simeticone and n-acetylcysteine significantly improves mucosal visibility during routine gastroscopy and also significantly reduces the need for flushes during the procedure to achieve adequate views.
- This may improve detection of early neoplasia and other pathology during gastroscopy.
- Subanalysis of separate locations demonstrates significant benefit in both the lower oesophagus and stomach, demonstrating potential benefit in Barrett's oesophagus surveillance procedures.