

National Institute for Health and Clinical Excellence

314 – Catheterless oesophageal pH monitoring

Comments table

IPAC date: 11 May 2006

Consultee name and organisation	Section no.	Comment no.	Comments	Response Please respond to all comments
BUPA	1 / 2.3 / 2.4 Provisional recommendations, Safety, Efficacy	1	BUPA disagrees. Might you have a look at * Fajardo NR et al Gastrointest Endosc 2006;63:184-5 re oesophageal perforation * Triester SL et al Gastrointest Endosc 2005;61:317-9 re severe chest pain * Bhat YM et al J Clin Gastroenterol 2006;40:116-21 and Alhawat SK et al J Clin Gastroenterol 2006;40:20-24 re significant chest pain, sometimes requiring removal. * Alhawat et al again re chest discomfort and foreign body sensations. * Bhat et al again and Wenner J et al Scan J Gastroenterol 2005;40:768-74 re device detachment within an hour (Bhat) and on the second day (Wenner, and receiver malfunction (both) * Bhat again re artefactually high levels of abnormal results in the first six hours after insertion?	<p>Fajardo NR et al will be cited in overview and guidance.</p> <p>Triester SL et al Not found in literature search; will order (case report only).</p> <p>Bhat YM et al Included in updated literature search.</p> <p>18/217 significant chest pain 3/217 capsule removal 7/217 early detachment 2/217 malfunction More events pH < 4 on day 1 (7%) than day 2 (5%)</p> <p>Alhawat et al 4/90 severe chest pain 3/90 removal Up to 66% foreign body discomfort</p>

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				<p>Wenner J et al Found in initial search, not included in table 2 2/57 early detachment 1/57 malfunction</p> <p>These complication rates are largely similar to those from studies included in table 2.</p> <p>Will cite Bhat (2006), Alhawati (2006) and Fajardo NR in table 2.</p> <p>Committee agreed to add a sentence to section 2.1.2 as follows: 'This technique may be used for patients who do not tolerate nasal intubation.'</p>
PROBE - Patient group of the Barretts Oesophagus Foundation	1 (provisional recommendations)	2	<p>This group of patients understand that NICE is currently recommending this procedure.</p> <p>"I believe it is generally clear what NICE is recommending about this procedure, but as a non-medical person, I cannot claim to fully understand the scientific and statistical terms used, e.g n=50, Kappa Statistic."</p>	Thank you, your comment has been noted.

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PROBE - Patient group of the Barretts Oesophagus Foundation	1 (provisional recommendations)	3	This group of patients find the idea of a catheterless system appealing, however the need for endoscopic placement is acknowledged and this has implications for additional Endoscopy procedures and therefore associated complications and discomfort. "the whole business an ordeal that reminds me of medieval and more recent torture methods!!!"	Noted – requirement for endoscopy will now be made clear in the 'Understanding NICE guidance: information for patients and carers' document.
PROBE - Patient group of the Barretts Oesophagus Foundation	1 (provisional recommendations)	4	"I feel that any attempt to improve diagnosis and effective treatment will be welcomed by patients, and the new procedure sounds as though it has good potential, so, if I were asked to undergo it, I would have no worries in agreeing to do so"	Thank you, your comment has been noted.
PROBE - Patient group of the Barretts Oesophagus Foundation	1 (provisional recommendations)	5	"I feel that any attempt to improve diagnosis and effective treatment will be welcomed by patients, and the new procedure sounds as though it has good potential, so, if I were asked to undergo it, I would have no worries in agreeing to do so"	Thank you, your comment has been noted.
PROBE - Patient group of the Barretts Oesophagus Foundation	1 (provisional recommendations)	6	"Patients appear to have been generally well informed and consent issues seem to have been dealt with, although, unless I have missed something, these points are not described in the paper."	Thank you, your comment has been noted.

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PROBE - Patient group of the Barretts Oesophagus Foundation	2.3 Efficacy	7	<p>Some of this patient group had experienced the traditional nasal placed catheter recording, one had taken part in a research project assessing the catheterless probe, some had not experienced either system. The 'hidden' nature of this recording device was very acceptable, ie able to 'carry on as normal'. The overall feedback was, understandably, that they would want more individual information. Again the need for endoscopic placement was noted. Examples of the feedback received are:-</p> <p>"Having undertaken the catheter based study I can vouch for it's discomfort and inconvenience and at first glance a catheterless based system clearly must have some advantages, however I note the need for endoscopy, incidence of chest pain as well as the issues recorded in paragraph 2.4.6 which clearly are of concern."</p> <p>"The information provided, and the protection and assurance to patients in the NICE report, seems to be very well defined, however some of the results suggest that this is a less accurate method of recording/identifying reflux episodes. Do we know why and does this mean, from our perspective, that early signs could be missed?"</p> <p>"Overall I think that it is a less invasive, presuming that one would be having endoscopies anyway, method of obtaining needed reflux data, providing of course that the data is sufficiently accurate. It will encourage a greater take up especially for repeat tests."</p>	Noted – requirement for endoscopy will now be made clear in the 'Understanding NICE guidance: information for patients' document.

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PROBE - Patient group of the Barretts Oesophagus Foundation	2.3 Efficacy	8	“Initially I would prefer catheterless over catheter, but would need to be reassured about the other complications before making a decision.”	Thank you, your comment has been noted.
PROBE - Patient group of the Barretts Oesophagus Foundation	2.3 Efficacy	9	“Having used the catheterless monitoring system, nearly 3 years ago, through Dr. XXXXX, I personally found no problems that I can recall. I also know I would not have liked the transnasal placement and would have been less inclined to take part.”	Thank you, your comment has been noted.
PROBE - Patient group of the Barretts Oesophagus Foundation	2.3 Efficacy	10	“Section2.3.3 seems to leave some questions unanswered. Is further research needed here ?”	Thank you, your comment has been noted.
PROBE - Patient group of the Barretts Oesophagus Foundation	2.4 Safety	11	“Initially I would prefer catheterless over catheter, but would need to be reassured about the other complications before making a decision.”	Thank you, your comment has been noted.
PROBE - Patient group of the Barretts Oesophagus Foundation	2.4 Safety	12	“Overall, research should be looking for even less intrusive methods, as both methods do not seem to be particularly appealing. Having a capsule attached to the oesophageal wall sounds as if it might damage it--in patients who are already worried about damage. It may need explaining more”	Thank you, your comment has been noted.
PROBE - Patient group of the Barretts Oesophagus Foundation	2.5 Other Comments	13	“Ultimately, one feels that an even more sophisticated technique would be more acceptable.(ultrasound?) However, patients are realistic and if the procedure helps to diagnose effectively, patients will support it.”	Thank you, your comment has been noted.

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PROBE - Patient group of the Barretts Oesophagus Foundation	2.5 Other Comments	14	“With the increase in technology it may be possible for the capsule transmitter to relay direct to a central recording site, thus saving individual recorders.”	Thank you, your comment has been noted.
PROBE - Patient group of the Barretts Oesophagus Foundation	2.5 Other Comments	15	“Anyway for me anything that avoids endoscopy and invasive techniques has got to be worth further research/investigation.”	Thank you, your comment has been noted.