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Cytosponge: a non-endoscopic diagnostic devise for patients at risk for oesophageal cancer - a case study of innovation to benefit patients

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Background

Oesophageal adenocarcinoma (OAC) has increased 6-fold since the 1990s. Barrett's Oesophagus (BE), the precursor lesion to OAC, can now be detected and treated endoscopically. This therefore offers the opportunity to prevent the development of OAC. However, most BE patients remain undiagnosed and even state of the art treatment would be ineffective at reducing mortality unless a safe, minimally invasive, affordable test is developed.

Over the past 10 years, Professor Fitzgerald and her team at Cambridge have developed a new non-endoscopic screening test called the Cytosponge "pill on a string" diagnostic and lab test (to detect molecular biomarkers) for the diagnosis of BE.

Methodology

All participants will swallow the Cytosponge device prior to having an endoscopy.

The Cytosponge is composed of a foam sphere, compressed within a capsule, attached to a string, which is swallowed by the patient. When it reaches the stomach, the capsule dissolves releasing sponge. The sponge remains attached to the string and is retrieved by pulling it, sweeping the inside of the oesophagus, collecting cells which can be used as a sample in the laboratory for biomarker analysis.

Results

The Cytosponge device was shown to be safe, well tolerated by patients and accurate at diagnosing BE with a sensitivity between 80% and 95%, in different studies, and a specificity of over 92%.

Furthermore, the device can be used in primary care.

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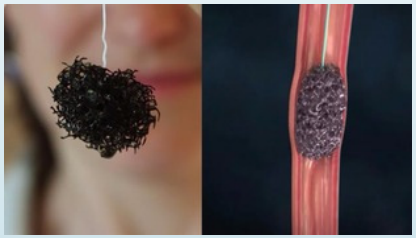

References

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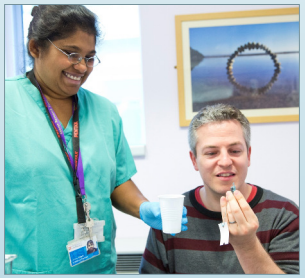
Contribution of the NIHR CRF

A high level of logistics and organization was required to complete these intensive studies in which patients could have up to three Cytosponge procedures and endoscopies. The CRF converted a former 2-bedded room into an endoscopy suite and trained their staff (including a nurse endoscopist) to support this work so that the studies could be delivered.

Over 1000 procedures were carried out over 5 studies.

The CRF staff and state of the art facilities have removed logistical and financial constraints in the main NHS enabling timely progression of the study and helped secure highly competitive grants.

Cambridge CRF support has been essential to enabling the progression of the Cytosponge from bench to bedside.



Conclusions and next steps

The study results have demonstrated safety, acceptability and high, clinically relevant sensitivity and specificity for the diagnostic test for Barrett's Oesophagus.

The next study planned (BEST3) will also utilise the CRF and will inform NICE approval for adoption as standard of clinical care.

The CRF expansion, due to open in 2017, will include an extended endoscopy facility.

Prof Fitzgerald and her team have been awarded the "BMJ Gastroenterology Team of the Year 2016".