Royal Cornwall Hospitals
NHS Trust

Oesophageal High Resolution Manometry and Ambulatory pH/ Impedance Monitoring Clinical Policy

V5.0

June 2024

Summary

Oesophageal physiology studies play an important role in the investigation and management of patients with oesophageal motility disorders as well as gastro-oesophageal reflux disease. Prior to the introduction of this service locally, patients were required to travel to Exeter.

This policy sets out the roles and responsibilities of those staff involved in delivering this service, the governance structure in place to support it, as well as details of how the procedure is performed.

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Data Protection Act 2018 (UK General Data Protection Regulation – GDPR) Legislation.

The Trust has a duty under the Data Protection Act 2018 and UK General Data Protection Regulations 2016/679 to ensure that there is a valid legal basis to process personal and sensitive data. The legal basis for processing must be identified and documented before the processing begins. In many cases we may need consent; this must be explicit, informed, and documented. We cannot rely on opt out, it must be opt in.

Data Protection Act 2018 and UK General Data Protection Regulations 2016/679 is applicable to all staff; this includes those working as contractors and providers of services.

For more information about your obligations under the Data Protection Act 2018 and UK General Data Protection Regulations 2016/679 please see the Information Use Framework Policy or contact the Information Governance Team.

Royal Cornwall Hospital Trust rch-tr.infogov@nhs.net

1. Introduction

1.1. Oesophageal manometry plays a vital role in the diagnostic pathway for patients with oesophageal motility disorders (e.g. achalasia, jackhammer oesophagus, distal oesophageal spasm) as well in the pre-operative evaluation of patients undergoing anti-reflux surgery.

1.2. High resolution manometry is the most advanced technology currently available for this purpose.

1.3. Oesophageal ambulatory pH monitoring is also a valuable tool to confirm or refute the presence of acid reflux, including in the pre-operative evaluation of patients requiring anti-reflux surgery.

1.4. Ambulatory impedance monitoring is utilised in patients with atypical reflux symptoms or who are refractory to proton pump inhibitors, to detect the presence of non-acid reflux where standard pH monitoring is inconclusive.

1.5. British Society of Gastroenterology guidelines (2019) recommend that all patients being considered for anti-reflux surgery should undergo both manometry and pH testing[1].

1.6. NICE-accredited commissioning guidance, published in September 2013, states that all patients undergoing anti-reflux surgery should have ready access to these investigations [2].

1.7. Prior to the introduction of this service locally at RCHT, these investigations were being performed at both Royal Devon and Exeter Hospital and Derriford Hospital.

1.8. This version supersedes any previous versions of this document.

2. Purpose of this Policy/Procedure

This document outlines the indications, contraindications and procedural policies relating to these investigations to ensure they are delivered safely, effectively and to the appropriate recognised standards.

3. Scope

This policy is relevant to the Consultant Upper Gastrointestinal (GI) Surgeon(s) interpreting and reporting the investigations, the nurse specialists performing the procedure, the administration booking staff and all those making referrals to this service.

4. Definitions/Glossary

4.1. High resolution manometry (HRM): Technique for assessing oesophageal motor function. Multiple pressure measurements are recorded using a water-perfused catheter, placed nasally into the oesophagus, to generate a topographical diagram.

4.2. Oesophageal pH monitoring: Technique using a catheter placed nasally into the oesophagus for assessing acid reflux within the oesophagus over a 24-hour period.

4.3. Catheterless oesophageal pH monitoring (Bravo®): Technique in which a detachable wireless capsule is 'stitched' in the oesophagus by endoscopy and enables wireless monitoring of oesophageal pH for up to 96 hours, for those patients unable to tolerate conventional pH monitoring.

4.4. Oesophageal impedance monitoring: Technique using a catheter placed nasally into the oesophagus for assessing non-acid reflux in patients with atypical symptoms or those refractory to proton pump inhibitor therapy.

4.5. Definitions

- AGIP – Association of Gastrointestinal Physiologists.
- BSG – British Society of Gastroenterology.
- MAXIMS – Trust electronic pathology and radiology reporting system.
- NICE – National Institute for Health and Care Excellence.
- OGD – Upper gastrointestinal endoscopy / oesophagogastroduodensocopy.
- PPI – proton pump inhibitor drug (e.g. omeprazole).
- RCHT – Royal Cornwall Hospitals NHS Trust.
- WHO – World Health Organisation.

5. Ownership and Responsibilities

5.1. The author of the document, Consultant Upper GI (UGI) and Bariatric Surgeon, will be responsible for ensuring the implementation of this service according to the standards of practice outlined in this document.

5.2. **Role of the Managers**

Line managers are responsible for:

- Supporting time in the job plans for nurse specialists and Consultant surgeon(s) to deliver this test.
- Setting up an appropriate clinic code and EROS ordering code for disposables.
- Ensuring clinical coding is appropriately set against the correct HRG tariff.

5.3. **Role of the Individual Staff**

5.3.1. **Secretary**

Secretaries are responsible for:

- Once a referral has been received and subsequently vetted by the upper GI surgery Consultant(s) or UGI specialist nurses , a date for the test will be offered to the patient.
- A patient appointment will then be scheduled.
- A letter will be sent to the patient, along with a patient information leaflet and GERD-HRQL questionnaire.
- Once a report has been uploaded by the Consultant UGI surgeon to the hard drive (S:/ drive) this will be uploaded to Maxims by the UGI secretary, and the referring Consultant informed.

5.3.2. **Clinical Nurse Specialist**

Clinical Nurse Specialist are responsible for:

- Setup the equipment in line with manufacturer guidelines and cleaning /preventive maintenance.
- Perform the procedure in line with the standards of practice outlined below and using the set protocol in Appendix 3a.
- Ensure storage of data confidentially on the Trust hard drive (S:/ drive).
- Ensuring ordering of disposables through EROS to maintain adequate stock.

5.3.3. **Consultant Upper GI Surgeon**

Consultant Upper GI Surgeon are responsible for:

- Perform the catheterless (Bravo®) insertion procedure in line with the procedural guide set out in Appendix 3b. Produce a report including the minimum dataset as listed in the BSG / AGIP guidelines1.
- Upload report to Trust hard drive (S:/ drive).
- Notify the UGI secretary once reports completed and uploaded.
- Where a test is deemed unsuitable due to a contraindication or relative contraindication it will be the responsibility of the upper GI surgery Consultant to discuss this with the referring Consultant.

5.3.4. **Coding staff**

Coding staff are responsible for:

- Ensure outpatient procedure codes recorded for relevant agreed HRG.

6. Standards and Practice

6.1. Referral process and patient selection

6.1.1. All referrals for conventional pH / manometry tests will be made using the electronic internal referral system on Maxims entitled 'Oesophageal pH / manometry Request Service.' This will not include requests for catheterless Bravo pH monitoring.

6.1.2. All referrals will be vetted weekly by the Consultant upper GI surgeon or specialist nurses, according to indications and contraindications set out in the AGIP and BSG guidelines.

6.1.3. All patients must have an OGD prior to referral for this investigation.

6.1.4. Where the test is deemed unsuitable the vetting Consultant will contact the referring Consultant to inform them of the reason.

6.1.5. Where conventional pH testing is not tolerated or where more extended pH monitoring is indicated, the Consultant UGI surgeon will arrange the catheterless Bravo insertion on an individual patient basis by adding the patient to the 'General Surgery Add to Waiting List Service' and an appropriate date scheduled.

6.2. Patient booking

6.2.1. Patients will have an appointment booked by the upper GI surgery secretary, confirmed on the phone with the patient.

6.2.2. Patients will be informed by post of their appointment.

6.2.3. A patient information leaflet (Appendix 4) will be sent to the patient, in addition to a quality of life questionnaire (GERD-HRQL).

6.3. Patient preparation

6.3.1. As per BSG guidelines, all anti-reflux medication will be stopped prior to the procedure as per the information leaflet, unless otherwise indicated (e.g. refractory to PPI therapy or having impedance studies).

6.2.4. Patients should be nil by mouth for six hours prior to the procedure.

6.2.5. In those with suspected achalasia a longer period of fasting may be required.

6.2.6. All patients will undergo Covid swab testing 72 hours prior to their procedure.

6.2.7. On admission for the test the patient details will be checked on arrival and written consent obtained prior to the start of the procedure.

6.2.8. Patients will be informed that they can withdraw consent at any time during the procedure.

6.2.9. Indications and contraindications for the test will be confirmed before proceeding. Where uncertainty arises this will be discussed with the supervising upper GI surgery Consultant(s) who will make a final decision.

6.4. **Equipment preparation**

6.4.1. The equipment will be checked by the nurse practitioner carrying out the test.

6.4.2. Calibration and zero of catheters as per manufacturer guidelines will be completed

6.4.3. Cleaning will be performed in line with manufacturer and local infection control guidance https://p1.aprimocdn.net/laborie/asset_id_194484_Original%20file.pdf (

6.4.4. For catheterless Bravo pH monitoring preparation will be in line with Appendix 3b.

6.4.5. Further disposables to be ordered via EROS using allocated code

6.5. **Procedure**

6.5.1. Staff will wear the appropriate protective clothing (in line with Public Health England advice).

6.5.2. Each step of the procedure will be explained to the patient.

6.5.3. Where application of local anaesthesia to the nares is required, this will be prescribed and administered by a member of staff with the appropriate qualification.

6.5.4. The procedure will follow a standardised protocol (appendix 3a and 3b).

6.5.5. Patients discharged with a pH / impedance monitor will be advised how to remove the nasogastric catheter by the nurse specialist. This will not be necessary for the catheterless bravo system.

6.5.6. The patient will be advised where to deliver the monitoring box for data analysis. The patient will receive a phone call from the nurse specialist in order to record the symptom diary.

6.6. **Post-procedure**

6.6.1. The single use water perfused HRM catheter and/or pH/impedance catheter should be placed straight into the appropriate coloured bag for disposal.

6.6.2. Analysis of the recording will be in line with the “Chicago Classification” for manometry (Appendix 6) and using Demeester score, symptom

index (SI) and symptom association probability (SAP) for pH / impedance studies.

6.6.3. Analysis will be performed by a trained upper GI surgeon.

6.6.4. Reporting will include the minimum dataset set out in the current BSG guidelines.

6.6.5. All studies will be uploaded direct to the RCH Shared Folder (S:/RCH-STO/Surgery/UpperGI/OesophagealManometry) and can then be analysed using the relevant software.

6.6.6. A PDF version of the report is then uploaded to the same Shared Folder (as above in 6.6.5) and a copy imported to Maxims 'Documents' folder.

6.6.7. The notes and a notification that the report is now uploaded, will be sent to the referring Consultant.

6.6.8. The outpatient outcome form is completed by the specialist nurse carrying out the procedure and then actioned by the upper GI secretary.

7. Dissemination and Implementation

1.1. The procedure will be performed by trained clinical nurse specialists.

1.2. All investigations will be interpreted by a trained Consultant UGI surgeon.

1.3. Ongoing supervision and mentorship will be offered by experienced gastroenterological support through Ardmore Health and Medtronic.

1.4. This policy will be presented at the surgical governance meeting, Divisional Governance meeting and subsequently uploaded to the intranet after approval.

1.5. This document can then be made accessible to all interested parties.

8. Monitoring compliance and effectiveness

Information Category	Detail of process and methodology for monitoring compliance
Element to be monitored	1. Length of time from referral to diagnostic test (RTT). 2. Volume and source of referrals. 3. Complications.
Lead	Michael Clarke, Consultant Upper GI, and Bariatric Surgeon.
Tool	1. Audit referral times to diagnostic. 2. Audit of volume / source of referrals. 3. Audit complications.
Frequency	Monitor annually.

Information Category	Detail of process and methodology for monitoring compliance
Reporting arrangements	Presented annually at the surgical directorate governance meeting.
Acting on recommendations and Lead(s)	Where action is required it will be the responsibility of the lead named above to coordinate and instigate these accordingly.
Change in practice and lessons to be shared	Lessons learned or changes to be made will be communicated to all service users through email and at local surgical directorate governance meeting.

9. Updating and Review

9.1. This policy will be reviewed in three years.

9.2. Revisions may be made ahead of the review date when the procedural document requires updating. Where the revisions are significant and the overall policy is changed, the revised document will be taken through the standard consultation, approval, and dissemination processes.

9.3. Where the revisions are minor, e.g. amended job titles or changes in the organisational structure, approval can be sought from the Executive Director responsible for signatory approval and can be re-published accordingly without having gone through the full consultation and ratification process.

9.4. Any revision activity will be recorded in the Version Control Table as part of the document control process.

10. Equality and Diversity

10.1. This document complies with the Royal Cornwall Hospitals NHS Trust service Equality and Diversity statement which can be found in the Equality Diversity And Inclusion Policy or the Equality and Diversity website.

10.2. Equality Impact Assessment

The Initial Equality Impact Assessment Screening Form is at Appendix 2.

Appendix 1. Governance Information

Information Category	Detailed Information
Document Title:	Oesophageal High Resolution Manometry and Ambulatory pH / Impedance Monitoring Clinical Policy V5.0
This document replaces (exact title of previous version):	Oesophageal High Resolution Manometry and Ambulatory pH / Impedance Monitoring Clinical Policy V4.0
Date Issued/Approved:	June 2024
Date Valid From:	June 2024
Date Valid To:	June 2027
Author/Owner:	Michael Clarke, Consultant Upper GI, and Bariatric Surgeon.
Contact details:	01872 252589
Brief summary of contents:	Policy outlining standards and procedures for providing this investigative procedure.
Suggested Keywords:	High resolution manometry / pH monitoring / impedance / gastrointestinal physiology / oesophageal.
Target Audience:	**RCHT:** Yes **CFT:** No **CIOS ICB:** No
Executive Director responsible for Policy:	Chief Medical Officer.
Approval route for consultation and ratification:	Specialty Governance meeting.
Manager confirming approval processes:	Ian McGowan.
Name of Governance Lead confirming consultation and ratification:	Suzanne Atkinson.
Links to key external standards:	None required.

Information Category	Detailed Information
Related Documents:	**References** 1. Trudgill NJ, Sifrim D, Sweis R et al. British Society of Gastroenterology guidelines for oesophageal manometry and oesophageal reflux monitoring. Gut 2019; 66:1-20. 2. Commissioning guide: Gastro-oesophageal reflux disease (GORD) 2013. Royal College of Surgeons of England / Association of Upper Gastrointestinal Surgeons of Great Britain and Ireland. Available at: http://www.rcseng.ac.uk/healthcare-bodies/docs/published-guides/gord
Training Need Identified:	No.
Publication Location (refer to Policy on Policies – Approvals and Ratification):	Internet and Intranet.
Document Library Folder/Sub Folder:	Clinical/Surgery.

Version Control Table

Date	Version Number	Summary of Changes	Changes Made by
22/05/2015	V1.0	Initial Issue.	Michael Clarke, Consultant Surgeon.
29/06/2015	V2.0	Added outpatient outcome form to Appendix.	Michael Clarke, Consultant Surgeon.
21/05/2018	V3.0	New Chicago classification, new e-referral system, new Shared folder for centralised storage of investigation data and reports. Appendices renumbered. Adjusted Appendix 3 including section on 'Data Upload'. Updated Governance Information and IEIA forms. Reference to Appendix 7 included.	Michael Clarke, Consultant Surgeon.
11/11/2020	V4.0	New section to include catheterless Bravo pH monitoring and changes to procedures due to Covid-19. Added new patient info leaflet.	Michael Clarke, Consultant Surgeon.
07/06/2024	V5.0	Updated protocol for oesphageal manometry in line with Chicago v4.0 in appendix 3a. Updated analysis flow diagram for Chicago	Michael Clarke, Consultant Upper

Date	Version Number	Summary of Changes	Changes Made by
		V4.0 appendix 5. Updated link for information on cleaning instructions section 6.4.3.	GI, and Bariatric Surgeon.

All or part of this document can be released under the Freedom of Information Act 2000.

All Policies, Strategies and Operating Procedures, including Business Plans, are to be kept for the lifetime of the organisation plus 6 years.

This document is only valid on the day of printing.

Controlled Document.

This document has been created following the Royal Cornwall Hospitals NHS Trust The Policy on Policies (Development and Management of Knowledge Procedural and Web Documents Policy). It should not be altered in any way without the express permission of the author or their Line Manager.

Appendix 2. Equality Impact Assessment

Section 1: Equality Impact Assessment (EIA) Form

The EIA process allows the Trust to identify where a policy or service may have a negative impact on an individual or particular group of people.

For guidance, please refer to the Equality Impact Assessment Policy (available from the document library) or contact the Equality, Diversity, and Inclusion Team rcht.inclusion@nhs.net

Information Category	Detailed Information
Name of the strategy/policy/proposal/service function to be assessed:	Oesophageal High Resolution Manometry and Ambulatory pH / Impedance Monitoring Clinical Policy V5.0
Department and Service Area:	Surgery, General Surgery and Cancer Services
Is this a new or existing document?	Existing
Name of individual completing EIA (Should be completed by an individual with a good understanding of the Service/Policy):	Michael Clarke, Consultant Upper GI, and Bariatric Surgeon.
Contact details:	01872 252589

Information Category	Detailed Information
1. Policy Aim - Who is the Policy aimed at? (The Policy is the Strategy, Policy, Proposal or Service Change to be assessed)	Outline standards and procedures for the delivery of this diagnostic test.
2. Policy Objectives	Understand why test will be carried out. Understand protocol for referral through to post-procedural care.
3. Policy Intended Outcomes	Enable safe delivery of oesophageal manometry and pH monitoring service.
4. How will you measure each outcome?	Referral to diagnostic test timing. Report accuracy. Patient tolerance.
5. Who is intended to benefit from the policy?	All members of staff involved in referring to or delivering this service.

Information Category	Detailed Information
6a. Who did you consult with? (Please select Yes or No for each category)	• Workforce: Yes • Patients/visitors: No • Local groups/system partners: No • External organisations: No • Other: No
6b. Please list the individuals/groups who have been consulted about this policy.	**Please record specific names of individuals/ groups:** Specialty Governance meeting
6c. What was the outcome of the consultation?	Approved
6d. Have you used any of the following to assist your assessment?	**National or local statistics, audits, activity reports, process maps, complaints, staff, or patient surveys:** No.

7. The Impact

Following consultation with key groups, has a negative impact been identified for any protected characteristic? Please note that a rationale is required for each one.

Where a negative impact is identified without rationale, the key groups will need to be consulted again.

Protected Characteristic	(Yes or No)	Rationale
Age	No	
Sex (male or female)	No	
Gender reassignment (Transgender, non-binary, gender fluid etc.)	No	
Race	No	
Disability (e.g. physical or cognitive impairment, mental health, long term conditions etc.)	No	
Religion or belief	No	
Marriage and civil partnership	No	

Protected Characteristic	(Yes or No)	Rationale
Pregnancy and maternity	No	
Sexual orientation (e.g. gay, straight, bisexual, lesbian etc.)	No	

A robust rationale must be in place for all protected characteristics. If a negative impact has been identified, please complete section 2. If no negative impact has been identified and if this is not a major service change, you can end the assessment here.

I am confident that section 2 of this EIA does not need completing as there are no highlighted risks of negative impact occurring because of this policy.

Name of person confirming result of initial impact assessment: Michael Clarke, Consultant Upper GI, and Bariatric Surgeon.

If a negative impact has been identified above OR this is a major service change, you will need to complete section 2 of the EIA form available here:
Section 2. Full Equality Analysis

Appendix 3a. Protocol for conducting oesophageal high resolution manometry and pH / impedance

Preparation

A) Equipment: Set-up, checks and calibration ‘zero’.

B) Patient: Check identity, patient history (including fasting and medications), consent form 3.

High resolution manometry

High Resolution Esophageal Manometry Standard Protocol: Chicago Classification version 4.0©

PRE-PROCEDURE:

Prior to procedure patients should fast for at least 4 hours and informed consent should be obtained.

The CC4.0 Working Group recommends using a solid state high-resolution.

manometry catheter with <2 cm sensor spacing with combined.

impedance sensors. However, the protocol and classification can be performed with water perfused catheters if appropriate.

normative values are used.

STUDY PROCEDURE

Study begins in supine position [use supine normative values].

• ≥60 seconds adaptation period.

• Document position with at least 3 deep inspirations.

• ≥30 seconds baseline period.

• 10 supine wet (5 ml) swallows.

• 1 multiple rapid swallow sequence (multiple rapid sequence may be repeated up to 3 sequences if failed attempt or abnormal response).

Change position to upright [use upright normative values].

• ≥60 seconds adaptation period.

• Document position with at least 3 deep inspirations.

• >30 seconds baseline period.

• ≥5 upright wet (5 ml) swallows.

• 1 rapid drink challenge.

If no clinically relevant motility disorder is found consider the following manometric tests.

• In a patient with high probability of a missed diagnosis, especially EGJ outflow obstruction: Solid test swallows, solid test meal, and/or pharmacologic provocation (ie, amyl nitrite, cholecystokinin) in the upright position to assess for obstruction.

• For suspected rumination/belching disorder: Post-prandial high-resolution impedance observation.

If equivocal results are found and/or there is suspicion for an EGJ outflow obstruction that does not fulfill criteria for achalasia, consider the following supportive tests.

• Timed barium esophagram, preferably with tablet.

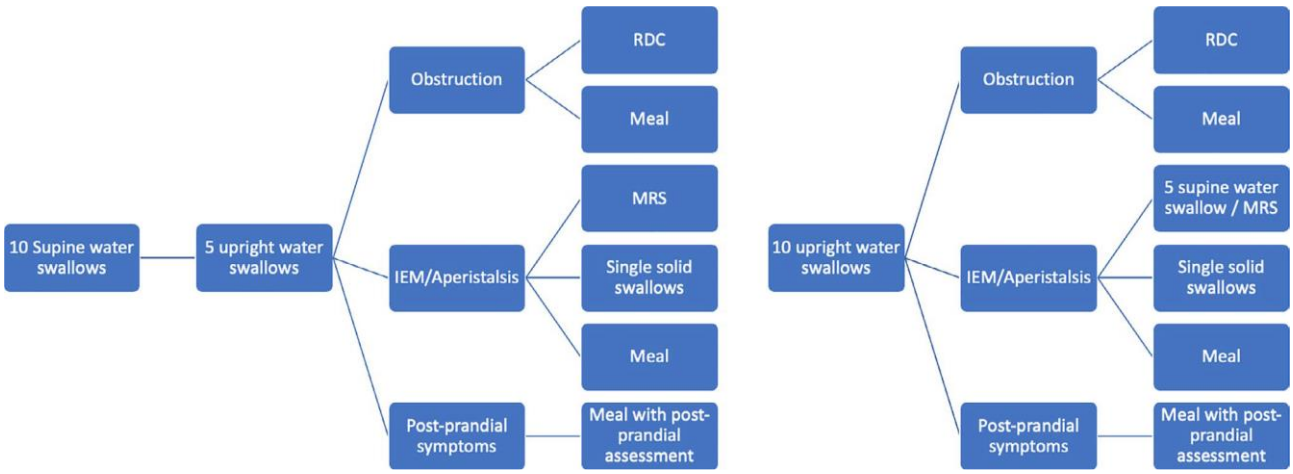
• Endoluminal functional lumen imaging planimetry (FLIP).

Although the protocol designed by the CC4.0 team is considered to be the optimal protocol, clinicians can modify this protocol based.

on limited resources and time as long as normative values are applied and other positions and provocative tests are used appropriately.

Physicians choosing to begin the study in the upright position should perform 10 upright swallows.

REPORTING: In addition to CC 3.0 metrics, final report should include baseline measures of the esophagogastric junction (EGJ) and symptoms experienced during the study and within 15 seconds of a motility dysfunction.



pH / impedance monitoring

A) Attach catheter to omega pH module.

B) pH catheter pre-soaked in each buffer solution following on-screen instructions.

C) Pass catheter via nose and position 5cm above top of lower-oesophageal sphincter.

E) Secure catheter to nose.

F) Provide symptom diary to patient and provide measuring box to patient with carrying bag.

G) Commence recording and arrange appointment following day for removal of catheter and download of data.

Data Upload

A) Upload data onto RCH Shared Drive (S:)/RCHSTO/Surgery/UpperGI/OesophagealManometry into the dated folder, along with a word document regarding the patient assessment and details of the tests conducted.

B) Information during consultation completed on generic Maxims document for oesophageal manometry and pH studies. Consent and patient diary scanned and uploaded to Maxims.

Coding

Day 1	Outpatient attendance (new).
Day 2	Outpatient attendance (follow-up).

Appendix 3b. Protocol for conducting catheterless (Bravo) pH monitoring

Step 1: Prepare the capsule delivery device.

1) Check the expiration date on the capsule.

2) Without bending or kinking the delivery device, carefully remove it from the external shipping box, and then from the inner pouch.

3) Remove the capsule's plastic cover, and magnetic clip. The capsule will automatically turn on when the magnetic clip is removed.

4) Set the magnetic clip aside.

5) After opening the capsule package, make sure the capsule trocar needle is not advanced.

Step 2: Prepare the vacuum pump.

1) Make sure the vacuum flow knob is turned to maximum.

2) With your gloved finger covering the suction chamber, verify that the vacuum gauge reading is at least 550 mmHg. Make a note of the gauge reading.

3) Remove your finger from the suction chamber. Verify that the vacuum gauge reading drops by at least 50 mmHg to 500 mmHg or lower.

4) Turn off the vacuum and detach the tubing from the delivery device.

Step 3: Start the recording.

1) If the recorder is turned off or in sleep mode, turn it on. Make sure it is fully charged.

2) From the main menu, select Start Study and press Enter.

3) If you see a "Last study not uploaded!" message, it means the recorder has detected existing data from a previous study that has not been uploaded.

4) To stop and upload the existing data, press Cancel and connect to the PC. Follow the instructions on the recorder. When the data is uploaded, start the new study again by selecting Start Study from the main menu.

5) To continue (overwrite the existing data without uploading it), press Next and then Yes to confirm.

6) The recorder will start searching for the capsule's signal, and the "Clearing data..." message will appear, followed by "Waiting for pH capsule 1".

7) When you see the message," Does this pH capsule ID number match the delivery device number?" Press Yes or No. You'll find the capsule ID on the package label. Bravo™ calibration- free reflux capsules have a 5-digit ID; Bravo™ reflux capsules have a 4-digit ID. If the ID doesn't match, the search will begin again.

8) If the recorder still does not recognize the capsule or displays a capsule mismatch error, repeat the procedure.

9) If this is a two-capsule study, repeat the process.

10) When capsule recorder pairing is complete, the recorder will automatically start recording and the screen will display the symptom buttons.

11) Verify that the recorder is displaying pH values and that the capsule status LED on the recorder is blinking blue.

Step 4: Place the capsule.

1) Determine the desired location for the capsule in the oesophagus:

Using an endoscope, the capsule is typically placed 6 cm above the squamo-columnar junction. Measure and record the distance travelled by the endoscope to the desired location.

Using a trans nasal manometry catheter, the capsule is typically placed 5 cm above the proximal aspect of the landmarks (LES). Use a correction factor of approximately 4 cm to account for the longer pathway that the manometry catheter has to travel through the nasopharynx.

2) Remove the endoscope from the patient.

3) With the vacuum off, complete the following steps:

Mark the placement location of the pH capsule on the delivery device. The depth markings on the delivery device are indexed from the capsule's pH sensor.

Carefully advance the delivery device through the mouth (with the capsule facing the patients' tongue) to the desired location in the oesophagus.

Holding the delivery device as straight as possible in a relaxed horizontal position, stabilize it by the patient's mouth to make sure it does not move.

4) Endoscopically check the oesophageal inlet to verify the desired placement of the delivery device in the oesophagus. Carefully remove the delivery device immediately if it has entered the trachea.

Step 5: Apply suction.

Apply suction to draw a small amount of tissue into the capsule’s suction chamber:

1) Attach the vacuum hose to the handle.

2) Turn on the vacuum source and verify that the gauge reading is the same you noted during vacuum setup.

3) After the vacuum level of at least 550 mmHg has been reached and the vacuum stabilized, allow 30 seconds for the tissue to fill the suction chamber.

Step 6: Attach capsule.

1) Remove the safety tab.

2) Swiftly press the plunger on top of the handle all the way down until it stops at its locking position. This will advance the trocar needle into the suction chamber.

3) Using your thumb, rotate the plunger from the side 1/8th of a turn clockwise to release the capsule from the delivery device. The plunger will spring up, so the white line is visible on the sixth rib of the plunger.

Step 7: Turn off vacuum source and remove delivery device.

Discard according to local waste management guidelines.

Step 8: Confirm.

At the clinician's discretion, endoscopically confirm the capsule's attachment.

Confirm that the recorder is recording pH values and the capsule status LED on the recorder is blinking blue.

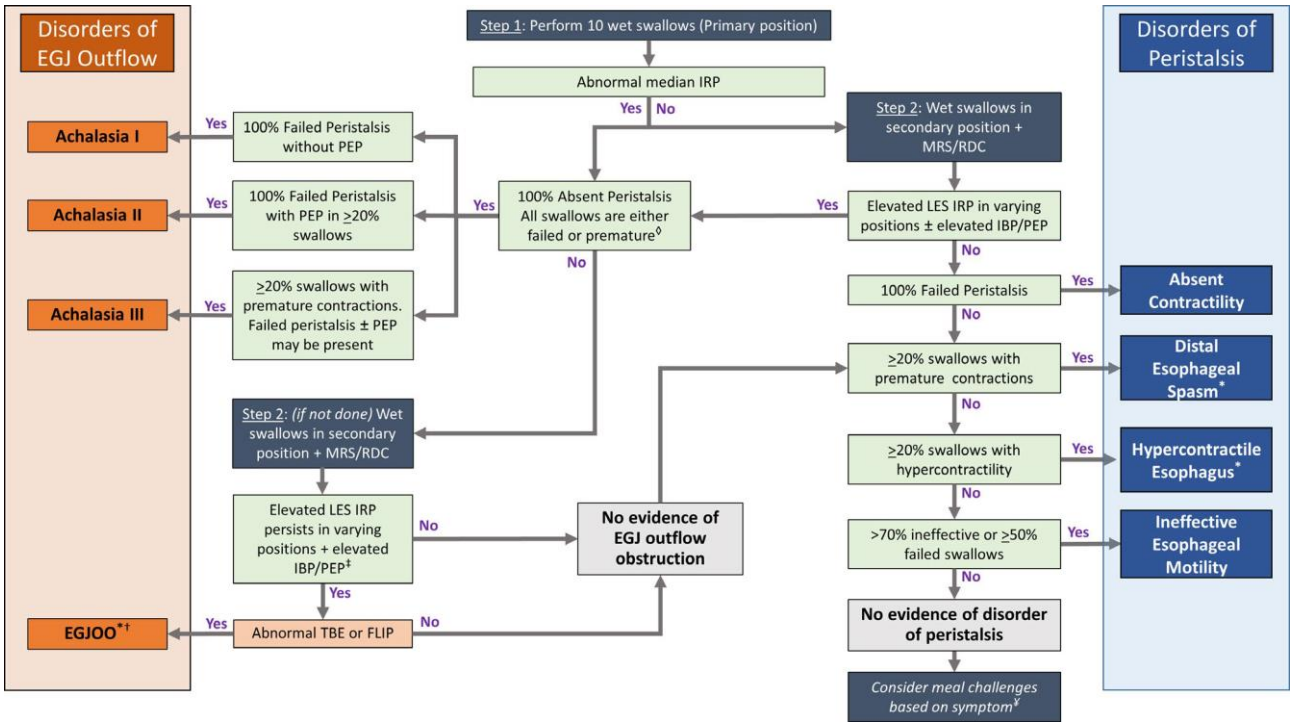
Appendix 4. Patient information leaflet; Oesophageal manometry and 24 hour pH monitoring (RCHT1503)

NHS
Royal Cornwall Hospitals
NHS Trust

Oesophageal manometry and pH monitoring

One + all | we care

Appendix 6. Chicago Classification version 4.0©



Yadlapati R, Kahrilas PJ, Fox MR et al. Esophageal motility disorders on high-resolution manometry:Chicago classification version 4.0© *Neurogastroenterology & Motility* (2020);33:e14058.