Gastro-oesophageal Reflux Monitoring – Patient Instructions

Target Audience	Professionals certified in the performance of oesophageal reflux monitoring
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This document provides guidance for GI Physiology professionals undertaking oesophageal reflux monitoring.

Catheter-Based reflux monitoring

Preferred Method

For ambulatory catheter-based reflux monitoring, the AGIP committee strongly recommends **ambulatory 24-hour pH impedance catheters** over single- or dual-channel pH only catheters. AGIP strongly recommends that Impedance-pH study is **only performed by skilled, accredited operators** who are able to accurately conduct a detailed, manual analysis of the data.

Both the AGIP Committee and the Lyon 2.0 Consensus advise against the use of single- or dual- channel pH only catheters. pH (without impedance) studies only detect acidic pH drops below pH 4, irrespective of if these are due to swallowing or true reflux. If these catheters are used, significant restrictions on patient behaviour during the testing period **must** be followed in order to have any meaningful data and to increase confidence in the obtained results (see below). However, there is still a significant risk of inaccurate, false positive results.

Multichannel Intraluminal Impedance-pH monitoring allows for assessment of direction of fluid-flow as well as content (liquid/gas), and careful analysis of this provides greater confidence in the validity of acid exposure time calculations. It also allows for assessment of other conditions (e.g. supragastric belching, aerophagia, rumination and others), whilst providing additional metrics that allow for a more accurate assessment of reflux (e.g. Mean Nocturnal Baseline Impedance; number of reflux episodes overall irrespective of acidity, reflux proximal extent). Further, it permits for reflux-symptom association measurements of both acid and non-acid reflux events separately. However, accuracy of Impedance pH monitoring relies on manual review. The AGIP Committee strongly advises that centres should **NOT** be using automated analysis alone. The automated measurements tend to over-estimate reflux related events. An inappropriately analysed study could result in patient harm and unnecessary surgery. Thus, adequate time in a quiet space, away from distractions and interruptions, needs to be provided to the professional to allow for detailed, manual review of the automated analysis.

Meals / Drinks

1. **pH Only Studies - (Wired or Wireless)**

If a pH study is performed without impedance (wired or wireless), it is essential that the patient follows a restricted diet during the study period.

For pH only studies, patients should follow these instructions when eating and drinking:

- Eat as normal, but minimise snacking and grazing as much as possible.
- Only drink plain water (not flavoured or carbonated), or non-acidic drinks (e.g. milk, or tea). Do not continuously sip drinks throughout the day.
- Avoid alcoholic drinks. If consumed, accurate documentation of start and finishing times with type of alcohol consumed is essential.
- Minimise sweets and avoid chewing chew gum in order to avoid unnecessary artefact of continuous swallowing. Document whatever is placed in the mouth so that it can be taken into consideration when reporting.

Rationale:

- Frequent sipping, snacking and grazing prolong ingestion periods, reducing the time available for accurate reflux assessment. It also increases artefact, making it technically difficult to be confident in measurements obtained. Mealtimes need to be manually blocked from analysis and excessive grazing reduces analysis periods.
- Acidic drinks may linger in the oesophagus, especially with poor motility. This leads to reduced measurement certainty and contributes to false positives, where the acidic contents pool around the pH sensor, long after the drinking period finished.
- The inability to measure direction of flow of swallowed fluids may be misinterpreted as an acid reflux if the fluid swallowed has a low pH (e.g. coke) and is not recorded beforehand.
- Carbonated drinks can lead to increased belching and gas transfer.
- Patients complete their paper diary sheets and press symptom buttons, but these approaches are not 100% reliable and discordance is not uncommon; meals and drinks are often missed or mis-recorded. These cannot be manually added in when reviewing the trace without impedance, and thus it is essential that steps are taken to minimise the likelihood of artefact by restricting diet and minimising acidic readings from meals/drinks.
- Excessive swallowing when chewing gum or sucking sweets can be associated with artefact of excessive clearance and/or belching so passive reflux cannot be reliably assessed.

Conclusion: For pH-only studies (if performed at all), **strict limitations on meals and drinks are essential.**

2. **Multichannel Intraluminal Impedance-pH monitoring**

AGIP strongly recommends that Impedance-pH study is only performed by skilled, accredited operators who are able to accurately conduct a detailed, manual analysis of the data. Automated analysis should not be used alone. With these provisions, the above strict limitations on meals and drinks are not essential if the aim is to reproduce normal

behaviour. However, if there is any doubt about the analytical skills of the operator, the above pH sensor dietary restrictions are recommended to increase confidence in obtained results.

If the patient does follow their normal diet with no restrictions, it is crucial that:

- accurate diary recording is **critical.** The patient should be made aware of this, so they understand the need to accurately record their meals and drinks. If this may be unreliable, then the strict dietary recommendations described above should be followed.
- the operator must correlate the recording with the diary entry carefully and annotate the trace as required to correlate with the diary before analysis. Missed or inaccurately recorded meals, drinks and position change should be inserted and/or edited where required before analysis can begin.
- careful manual analysis of the recording must then follow automated analysis; there is an increased risk of overinterpretation with automated analysis leading to false positives outcomes, particularly with symptom association.

Other Patient Instructions

The following apply for all methods of assessment (Multichannel Intraluminal Impedance-pH monitoring, single- or dual-channel pH only catheters, Wireless pH monitoring):

1. **Sleeping**

The patient should try to lay flat when in bed, using just one pillow and avoid propping themselves up. This ensures that the sleep period is a true supine assessment of reflux. Further, supine periods do not necessarily have to be at night when the patient is asleep. All supine periods should be recorded.

2. **Activity**

The patient should be encouraged to have as normal a day as possible, maintaining their normal activity levels. Resting all day is not recommended (unless this is reflective of their normal behaviour), but any strenuous physical activity should be recorded.

The patient should avoid getting the recorder wet (no showers/baths/swimming). With wireless pH monitoring, the recorder can be placed nearby but not under the shower.

Upon removal of the equipment, it is useful to ascertain if normal behaviour and activity was maintained, how well the patient tolerated the investigation, and if symptoms during the study period were typical for the patient. Having a 'good day' should be noted as should intolerance leading to reduced activity. It is possible to extend the study for more than one day if it is deemed appropriate and the patient is willing to continue.

3. **Medication**

Any medications discontinued in advance of this investigation (e.g. PPIs, H2 Receptor Antagonists or antacids) **must not be taken during the study period**. They may be restarted once the test is complete.

If a Multichannel Intraluminal Impedance-pH study is being performed **on therapy**, the patient should continue taking their medications as usual, but this should have been agreed in advance. If the patient takes such medicines during the study, it should be clearly documented.

If a patient is on weight loss medication (GLP-1 agonists e.g. Mounjaro, Wygovy and similar), this needs to be well documented as it could be contributing to their symptoms. Although we do not require these medications to be stopped for pH testing, they are known to lead to delayed gastric emptying and reflux.

Post-Study

For ambulatory catheter-based assessment, it is useful to ask the patient how they perceived the 24-hour testing period. This can help to determine if repeat testing, or a prolonged wireless study, would be beneficial. The information can be obtained verbally or through a formal questionnaire, to determine:

- patient tolerance.
- patient activity/behaviour - to assess if it was a "normal" day for the patient.
- symptoms - to determine if representative of the patient's normal experience.