Correlation between oesophageal diameter, patient age, oesophagitis and pH measurements

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Declaration

I declare that all the written work that follows including analysis and interpretation of data is entirely mine and was performed under the guidance of Mr R F McCloy and Dr K R Haylett.
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2. Abstract

**Background and Aims:** Gastro-oesophageal reflux disease is characterised by abnormal reflux and its pathophysiology is multifactorial. Important mechanisms include dysfunction of the lower oesophageal sphincter, impaired oesophageal clearance and the presence of a hiatus hernia. There is limited knowledge of the role played by oesophageal lumen diameter. The aim of this study is to investigate the relationship between oesophageal diameter, age, oesophagitis and pH measurement.

**Methods:** The lumen diameter of patients with oesophageal disorders were measured using fluoromanometry. The overall widest diameter, together with the widest diameter at the most distal transducer was measured for five controlled swallows. These results were critically analysed with the current measures of acid exposure, obtained from the GI database, and reports from endoscopy.

**Results:** The results showed that the maximum lumen diameter increased significantly with age (p=0.0007). No difference was noted between patients with oesophagitis, with respect to measures of acid exposure and maximum lumen diameter. However, there was a significant difference in estimated clearance of patients with a hiatus hernia (p=0.029 student t test).

**Conclusion:** There is a structural change of the oesophagus with ageing. This difference was stronger in patients with oesophagitis. The wider diameter may be a result of disease and provide a clue to as yet an unknown pathophysiological factor. Interestingly estimated clearance seemed to be improved by the presence of hiatal hernias. Understanding these factors together with improvements in the diagnostic investigations are key to successful management of the patient.
3. Introduction

Gastro-oesophageal reflux (GOR) is a term used to describe retrograde passage of stomach contents into the oesophagus and is a normal occurrence especially after eating. Gastro-oesophageal reflux disease (GORD) is a syndrome with a world wide distribution and is caused by abnormal GOR. Typical symptoms include heartburn, regurgitation and odynophagia. Heartburn is described as a retrosternal burning sensation that radiates to the throat. It usually occurs after meals, whilst bending down or lying flat. Regurgitation is the effortless re-emergence of undigested material from the stomach to the mouth, and odynophagia is the sensation of pain felt behind the sternum during swallowing. Abnormal reflux of acidic stomach contents leads to inflammation of the lining of the oesophagus, and hence reflux oesophagitis is one of the complications of GORD. More severe damage may result in oesophageal ulcerations, strictures and Barrett’s metaplasia.

GORD has a wide spectrum of manifestations including those which are extra-oesophageal, such as oral, otolaryngologic and pulmonary. Oesophageal manifestations include Endoscopy-negative reflux disease (ENRD), oesophagitis and unexplained chest pain. It is important to understand this wide spectrum in order to choose the most useful and informative diagnostic tool available and to optimise patient management.

3.1. Pathophysiology of GORD

3.1.1. The Antireflux barrier

The distal 4cm of the oesophagus has a high resting tone and is known as the lower oesophageal sphincter (LOS). The LOS provides one of the most important antireflux mechanisms, and LOS competence is a primary factor in the prevention of GORD. It is composed of visceral smooth muscle and is formed by thickening of the muscularis propria in the distal oesophagus. The main functions of the LOS are to (a) maintain a high pressure thus preventing reflux, and (b) to relax at times to allow the passage of a swallowed bolus. These functions result from the intrinsic tone of the
Several hypotheses have been proposed to explain the mechanisms of LOS involvement. Cohen and Harris (1970) stated that hypotonia of the LOS was the major cause of GOR and thus oesophagitis. However, it was noticed that the majority of patients with GORD had a normal basal LOS pressure.

Another widely accepted hypothesis is that of transient lower oesophageal sphincter relaxations (TLOSR). These TLOSR occur despite a normal pressure in the LOS and results in episodes of GOR. It has been proposed that stretch stimuli to part of the stomach adjacent the LOS causes TLOSR, mediated by vagal pathways. This might explain why fundoplication is effective in preventing GOR, as it prevents stretching of the fundus and thus inhibit the vagal reflex.

A number of substances can act to decrease the basal LOS pressure. For example, foods (chocolate and ethanol) and pharmacological agents (anticholinergics and dopamine). Pregnancy is also associated with GORD and is thought to be caused by the increased abdominal pressure exceeding the LOS pressure, and by additional hormones reducing the sphincter pressure further. Pathological conditions associated with LOS incompetence include those diseases that affect smooth muscle, such as scleroderma, diabetes mellitus and hypothyroidism.

3.1.2. Oesophageal Clearance

When gastric contents overcome the antireflux barriers, the second line of defence is oesophageal clearance. The components which make up this defence system include peristalsis to clear the oesophagus and swallowed saliva to neutralise acid. There are two main types of peristalsis, primary and secondary. Primary peristalsis is elicited by deglutition and is necessary for complete oesophageal clearance. Secondary peristalsis results from distension and mucosal irritation, and contributes to decreased oesophageal volume but not to the extent of primary peristalsis. In addition, the actual force of peristaltic contraction has been correlated with contraction amplitude and shown to be important in oesophageal clearance.

The main component of saliva, bicarbonate \((\text{HCO}_3^-)\), is directly related to its acid buffering capacity. This together with the rate of production and volume of saliva are important aspects to consider when assessing its protective benefit. Interestingly,
Moazzez et al (2003) recently concluded that chewing a piece of gum for half an hour after a meal significantly reduced oesophageal acid exposure. The proposed mechanism, chewing gum stimulates saliva production and initiates primary peristalsis, and thus assists in neutralisation and clearance of oesophageal acid.

3.1.3. Oesophageal Epithelium

The protective benefits of the above mechanisms are not effective during sleep, thus any gastric contents in contact with oesophageal epithelium have increased detrimental capability. However, it has been found that the exposure of the oesophageal epithelium to hydrochloric acid for substantial periods of time, resulted in little or no change to the epithelium. This points to the existence of other defence mechanisms. These can be divided into three different groups:

**Pre-epithelial defence** - Mucus composed of high-molecular-weight glycoproteins prevents pepsin from gaining access to the underlying epithelium. It does not however, efficiently prevent the access of hydrogen ions (H⁺) but is involved in expanding the unstirred water layer. The unstirred water layer creates an alkaline environment close to the epithelium by acting as a HCO₃⁻ sink and thus neutralising H⁺.

**Epithelial** - The lining of the oesophagus is a non-keratinized stratified squamous epithelium. Tight junctions and lamellar-lipid material that fills the intercellular spaces of the deeper layers of the stratum corneum, provide a major barrier to ions and molecules.

**Post-epithelial** - The blood supply is important for normal acid-base balance, supplying HCO₃⁻ and removing noxious by-products such as CO₂ and acids. The amount of blood supply can change in response to the level of the threat. However, if this exceeds the blood supply this eventually leads to cell necrosis.
3.1.4. **Hiatus Hernia**

Within the literature the relationship between hiatus hernia (HH) and GORD remains controversial. Earlier studies based their theories around the idea that antireflux mechanisms were compromised due to the intrathoracic location of the gastro-oesophageal junction. However, the age-related increase in HH without a corresponding rise in frequency of GORD presented a paradox. More recently a statistically significant relationship has been found between abnormal pH monitoring in individuals with larger hiatal hernias, compared to those with minimal size hiatal hernias. It has been contemplated that HH alters the function of the LOS and impairs oesophageal emptying (Figure 1). Uncertainty may have arisen when comparing studies on hiatal hernias due to having populations that differ in prevalence of oesophagitis and having different criteria for diagnosing hiatus hernia.

![Figure 1](image_url) A large hiatus hernia can weaken the ‘pinchcock’ antireflux mechanism of the diaphragm.

3.1.5. **Gastric Volume**

It has been found that increased gastric volume results in an increase in TLOSR, by causing distension. Gastric volume is influenced by gastric secretory rate, emptying and reflux. One study observed a decreased rate of gastric emptying in patients with reflux, possibly due to an interaction between gastric emptying and LOS pressure. However, another study found no correlation between gastric emptying and oesophagitis. This discrepancy and the uncertainty of the relationship between gastric emptying and GOR might have arisen because neither of the studies continuously monitored LOS pressure.
3.1.6. Other Factors

It is not only the volume and frequency of GOR that determines how damaging it will be, the composition is also important. Medication such as aspirin can be very damaging especially if reflux occurs soon after the aspirin has digested in the gastric contents.\textsuperscript{11} Some foods and drinks may reduce acid pH although most have a buffering affect. Increased pepsin concentrations further enhance damage caused by acid. The same is true of bile salts and bile acids from duodenogastric reflux, which can damage the oesophageal mucosal barrier.

\textbf{Figure 2.} Summary of factors in GORD

3.2. Oesophagitis and Diagnosis of GORD

The majority of patients with GORD are not investigated by gastroenterologists as they treat themselves with over the counter medication or are treated by their general practitioner (GP). Oesophagitis is a complication of GORD; longstanding oesophagitis heals by scarring and may form what is known as an oesophageal stricture. However, the presence of oesophagitis is not necessary for the diagnosis of GORD.\textsuperscript{12} The majority of patients referred to a gastroenterologist with symptoms of GORD are investigated thoroughly as to understand the underlying pathophysiology before long term treatment options are considered. The most frequent investigations implemented include endoscopy, fluoroscopy, 24 hour pH monitoring and oesophageal manometry. Investigations such as gastric emptying tests, measures of bilirubin exposure and more recently fluoromanometry\textsuperscript{13}, are
reserved for when there is an atypical history and results of standard investigations have been unclear.

3.2.1. 24 hour ambulatory pH monitoring

The ‘gold standard’ for detecting and confirming GORD for more than 25 years is 24 hour ambulatory pH monitoring. As well as on clinical grounds it is also frequently used as a research tool to try and further the understanding of the complex relationship between pH and GORD.

A catheter with a small pH probe is calibrated using buffer solutions at first pH 7 and then pH 1. The catheter is introduced nasally and the probe positioned 5cm above the LOS in the lumen of the oesophagus. A position of greater than 5cm reduces the sensitivity of the test, and less than 3cm would greatly increase the probability of probe displacement into the stomach.

In the GI investigation unit (Manchester Royal Infirmary), localization of the LOS is done manometrically by standard pull through investigation. This is the most widely accepted and accurate method. It involves withdrawing the manometry catheter by increments of 1cm, recording at each level several swallow induced relaxations over a period of around 20mins. The site of the LOS is confirmed when there is a significant drop in pressure.

Alternative techniques are used in some centres. For example recording when there is a pH step up, occurring when the probe is removed from the stomach and drawn across the cardia. Previously, fluoroscopic and endoscopic localisation of the LOS have not proved effective and has largely been abandoned.

The pH probe records the pH over a period of 24 hours. It is connected to a solid state data recorder worn around the patient’s waist. At the end of the 24 hour period, the data recorder can be connected to a computer where the data is uploaded and can be analysed using appropriate software. Reflux into the oesophagus is detected when the pH drops below 4. One of the principle analyses carried out is the total percentage time the pH is below 4 over the 24 hour period. It is considered abnormal if this percentage is ≥6 and is one of the simplest variables utilized in the diagnosis of GORD. Johnson and DeMeester (1974) derived a composite score for the features obtained from 24 hour pH monitoring, allowing for an alternative interpretation of the data. Other features analysed are shown in Table 1.
During the 24 hour investigation, patients are advised to take part in normal activities, and to eat and drink normally with the exception of drinks with a low pH such as fruit juices. Patients are also asked to keep a diary of their activities and symptoms over the 24 hour period, as this can latter be correlated with data from the recorder. Proton Pump Inhibitors such as lansoprazole (Zoton, Lederle, UK) and omeprazole (Losec, AstraZeneca, UK) should be stopped 7 days prior to the test.

Several studies have shown that 24 hour pH monitoring demonstrates good discrimination between normal controls and patients with oesophagitis. However, a recent review of the diagnostic techniques in GORD has highlighted that pH monitoring has a variety of limitations. Some of these include:

- a large variation (3.2 fold) in total percentage time pH<4. Hence considerable controversy exists about the reproducibility of 24 hour pH monitoring;
- 25% of patients with endoscopy proven oesophagitis have normal 24 hour pH analysis results;
- an overlap between endoscopy-negative reflux disease and normal controls, thus making data collected far less reliable;
- problems with the final analysis of the raw data.

GORD exists as a result of many factors and pH monitoring measures only one pathophysiological variable. Interestingly, despite the limitations, 24 hour ambulatory
pH monitoring remains the ‘gold standard’ for investigating the levels of gastro-oesophageal acid reflux.

3.2.2. Endoscopy

This investigational tool allows direct visualisation of the oesophagus. As well as detailed investigation of the mucosal walls, it also facilitates the detection of strictures. With the aid of a local anaesthetic the endoscope is introduced via the mouth of the patient. Endoscopically, oesophagitis is seen as areas of erythema with a number of red streaks and erosions typically in the distal part of the oesophagus.20 These red streaks can be biopsied and sent for histology. The streaks occur more frequently at the top of the mucosal folds and have been confirmed to be the site of mucosal injury.20 When the oesophageal lumen is collapsed, there are a greater number of mucosal folds.21 Thus red streaks seen at endoscopy suggest increased contact with gastric contents along the top of the mucosal folds (Figure 3).

Due to the anatomy of the oesophagus, areas of mucosa are exposed to different levels of pH depending on the volume of acid within the folds. Hence, this points to the presence of a variable pH microclimate in the oesophagus, which has been shown in a study that recorded different pH values using two probes located at the same level.22

![Diagram of oesophageal morphology and endoscopy demonstrating red streaks of oesophagitis](image)

**Figure 3.** Diagrammatic representation of oesophageal morphology and Endoscopy demonstrating red streaks of oesophagitis
Endoscopy is also used to grade the severity of oesophagitis. However, problems arise due to the lack of an approved standardised classification system. More than 30 different systems are used worldwide, none of which are accepted by everyone.¹

3.2.3. **Fluoroscopy**

This is a radiological investigation used for imaging the anatomy of the oesophagus. The patient swallows a solution of barium, whilst being monitored using an image intensifier. Its main role in GORD is to assess an inadequate antireflux mechanism, that is to observe gastro-oesophageal reflux.²³ It is extremely good at visualising and thus diagnosing hiatal hernias and oesophageal strictures. Consequently there has been a renewed interest in radiology, as the importance of hiatus hernia involvement in prolonging oesophageal acid exposure is becoming increasingly recognised.²⁴

Fluoroscopic barium studies are extremely good at evaluating GORD patients with dysphagia but are otherwise of limited use in GORD patients.¹ It has a lower sensitivity than pH monitoring in the diagnosis of GORD, but this sensitivity can be increased by the use of provocative techniques such as the Valsalva manoeuvre or using the water-siphon test. This involves the patient swallowing water after the stomach is filled with barium, and is positive if reflux of barium into the oesophagus occurs. However, these techniques reduce the specificity of the fluoroscopic barium studies.²³

3.2.4. **Manometry**

Oesophageal manometry is used to investigate peristalsis and LOS competence. A catheter with pressure transducers located along its length is inserted nasally into the oesophagus. As well as allowing the accurate determination of the LOS for use with 24 hour pH monitoring, it is used for investigation of motility disorders of the oesophagus. It is of limited value in the diagnosis of GORD but can identify GORD in the presence of a hypotensive lower oesophageal sphincter.²⁵
3.2.5. Combining fluoroscopy and manometry

This new investigational tool synchronizes the video fluoroscopic barium swallow examination with the oesophageal manometry. The manometry catheter is inserted first and then the patient is taken to the radiology suite where they are asked to swallow barium solution. It allows a deeper understanding of the relationship between bolus transport and pressure waveforms, which do not always correlate.  

3.3. Management of GORD

There are three main strategies that can be implemented in the management of GORD. The first should be lifestyle changes, but this may prove difficult for the patient to maintain. Certain food should be avoided, such as high fat foods (cheese etc.). Body weight should be brought down to the ideal and meals should be small and frequent. Avoiding lying down 3 hours after meals, raising the head of the bed and stopping smoking have all shown to be beneficial in reducing exposure of the oesophagus to acid.

3.3.1. Medical

A wide variety of medications are available over the counter. These include antacids that provide good symptomatic relief, although are of limited value, for long term neutralisation of acid. Parietal cells secrete acid and can be stimulated by histamine binding to H₂ receptors on their surface. Histamine (H₂) receptor antagonists (e.g. cimetidine, ranitidine) are particularly useful when taken as premedication before partaking in an activity that causes reflux. The volume and contents of acid in the refluxate is thus reduced by H₂ receptor antagonists. Stronger doses of H₂ receptor antagonists are available on prescription.

Another major class of drugs used for acid suppression are Proton Pump Inhibitors, for example omeprazole. These drugs act by blocking the Na⁺ K⁺ ATPase found on parietal cells, resulting in the inhibition of acid production.

Prokinetic drugs act by influencing motility of the oesophagus. An example is cisapride which improves reflux by enhancing peristaltic contractions, increasing LOS pressure and augmenting gastric emptying. Studies have suggested a combination of
medical treatments have a beneficial role, for example in patients who show 
resistance to H₂ antagonists alone, combining a prokinetic agent and H₂ antagonist is 
promising.²⁷

Medical therapy can be very successful in the treatment of GORD symptoms 
but the relapse rate can be high, often leaving patients on lifelong medication. In 
addition, medical therapy is not as effective in treating severe oesophagitis, and when 
there is a defective LOS, a different approach to management is required.

3.3.2. Surgical

Medical therapy in the treatment of GORD is directed at acid neutralisation, 
reducing acid secretion and improving the efficiency of oesophageal acid clearance. 
Surgery is used to try and support the LOS acting as a barrier to reflux. Laparoscopic 
techniques have a higher patient acceptance with less morbidity and mortality than the 
open procedures.²⁸ Some of the indications include:

- patients who are refractory to medical therapy;

- patients with a progressive disease requiring increasing doses of medication;

- patient age. Coley et al. (1993)²⁹ demonstrated a cost advantage over medical 
therapy in patients younger than 49.

Many antireflux procedures have been described. One of the first successful 
and still widely used to this date is the Nissen fundoplication (1956)²⁸. This involves 
wrapping the gastric fundus 360° around the lower oesophagus. The aim is to mobilise 
the fundus so that it relaxes with the LOS on swallowing. The length and resting 
pressure of the LOS is increased and subsequently results in a reduction in reflux. If 
the fundus becomes attached to surrounding structures the patient may have 
postoperative dysphagia.³⁰ Other complications that may arise from this procedure 
include oesophageal and gastric perforation, pneumothorax, injury to major vessels 
and cardiac laceration. However, studies reveal high success rates, a Swedish study 
reported fewer than 10% of patients had recurrent reflux 10 years later.³¹
The severity of symptoms do not always correspond to information gathered from investigations, such as pH monitoring and endoscopy. For this reason the clinical decision on whether to perform surgery and what procedures to use maybe difficult, and in some cases reversal of the procedure may become necessary.

3.4. **Presbyoesophagus and Presbyphagia**

The concept of presbyoesophagus is controversial. Originally the term was used to define oesophageal motility disorder associated with ageing. Manometrically this included a decrease in contractile amplitude, increased non-peristaltic contractions, incomplete LOS relaxations and oesophageal dilatation.\(^{32}\) However, this concept has been abandoned as it was thought these changes were more related to underlying medical conditions such as diabetes mellitus and neurological disorders that occur more commonly with ageing.\(^{33}\)

Dysphagia is a condition in which swallowing is difficult. Studies have highlighted an increased incidence of dysphagia in the elderly.\(^{34}\) Primary presbyphagia is the term used to describe the effects of normal ageing on swallowing, whereas secondary presbyphagia describes the effects of diseases, for example cerebrovascular accidents or Parkinson’s disease. In patients over the age of 50, 10% reported dysphagia.\(^{33}\) Reasons for this high rate are not known, and previous studies in asymptomatic patients have shown only minimal age related changes.

3.5. **Objectives**

GORD is a multifactorial disease and significantly reduces the quality of life of millions of people around the world. Billions are spent on its management and as yet the underlying pathophysiology is not fully understood. Important life changing clinical decisions are made everyday on our limited understanding of this disease.

The aims of this study are firstly, to examine the relationship between oesophageal lumen diameter, age, oesophagitis and ambulatory 24 hour pH measurements. Secondly, to determine if it is possible to improve the measurement of pH and acid exposure by combining the total exposure time with the maximum lumen diameter.
3.6 Hypotheses

Controversy exists around the concept that ageing significantly affects the oesophagus.\textsuperscript{33} Our first hypothesis is:

1. The musculature of the oesophagus changes with age and as a result affects the lumen diameter.

Evidence from endoscopy and radiology show when the oesophageal lumen is collapsed a number of mucosal folds are formed.\textsuperscript{21} Thus different areas of the mucosa are exposed to different amounts of acid.

2. The maximum lumen diameter may be larger in those patients with oesophagitis, as there will be minimal luminal collapse and hence increased mucosal acid exposure.

24 hour pH monitoring is the ‘gold standard’ for the investigation of GORD. However, acid reflux has been shown to be a poor predictor of oesophagitis.\textsuperscript{35}

3. There is no difference between 24 hour pH results between patients with and without oesophagitis.

Oesophageal clearance and hiatus hernia are important factors in the pathophysiology of GORD.\textsuperscript{5}

4. Those patients with pathological reflux have reduced oesophageal clearance and may have different lumen diameters.

5. In those patients with oesophagitis there will be a greater chance of diagnosing a hiatus hernia.

In the investigations of GORD, the area of the oesophagus exposed to acid is not considered. As yet it is not possible to measure the area but it is possible to approximately measure the diameter.
6. Combining percentage time exposed with lumen diameter may provide a closer representation of exposure of the lumen wall with acid and hence will differentiate between those patients with and without oesophagitis.

4. Materials and Methods

4.1. Patient selection

The study was retrospective and all the patients selected had undergone full investigations for GORD and dysphagia. This included 24 hour ambulatory pH monitoring, endoscopy and fluoromanometry. There were a total of 52 investigations. However, 9/26 of the GORD group and 2/16 of the dysphagia group were not useful due to missing information.

4.2. Measuring lumen diameter

Fluoromanometry is a new investigational tool developed at Manchester Royal Infirmary (U.K) that synchronises the video image of the barium swallow with the manometry data of the pressures within the oesophagus. A manometry catheter with four transducers located 5cm apart (Gaeltec Ltd, UK) was intubated trans-nasally. The most distal transducer (P4) positioned 3cm above the LOS (detected manometrically). This study enabled a frame by frame review of the barium swallow whilst allowing a close investigation of the relationship between manometry and swallowing. Concurrently the measurement of oesophageal lumen diameters using an on-screen ruler were carried out. The ruler was calibrated from the distance between the centres of the manometry transducers. The sites of each of the four probes were tagged with electronic markers as during the swallow the probes become obscured by the barium (Figure 4). Hence the electronic markers became the reference point for measuring lumen diameters between each swallow.

The screen size was set at ¾ for each patient swallow to provide consistency of the measurements. In each study the patient was asked to swallow 5ml of barium in the erect position. After each swallow an interval of greater than 30 seconds was
allowed for the swallowing reflex to recover. More rapid swallows might be misinterpreted as an abnormality as primary peristalsis may be inhibited. A total of five controlled swallows for each patient was carried out, as this had been shown to be the minimum required for an accurate assessment of motility.

During each swallow the widest diameters at each of the probes was recorded together with the widest region of barium in the distal region below P2 (Figure 4). This is the region where oesophagitis is commonly seen during endoscopy. It is important to note that the radiology shows only a single plane and therefore the measurement is an estimate as the lumen may be elliptical or deformed. The location of the widest diameter was also measured with reference to the position of P4. An estimated percentage clearance was also recorded, for each of the five swallows, by visually assessing the amount of barium remaining in the oesophagus once the swallow was complete.

Figure 4. Measuring the lumen diameter

4.3. 24 hour pH-metry

After patients had been investigated with fluoromanometry, a pH probe (Zinetics 24) was inserted trans-nasally and 24 hour pH studies were carried out with the patient coming back the following day for removal of the catheter, and uploading of the data from the solid state recorder (digitrapper MKIII). The results were entered into the GI investigations database. The pH results were accessed and collected from
the GI database. The percentage fraction time pH<4 was recorded from hardcopies of the pH results as this value was not recorded on the database.

Figure 5. Example of 24 hour pH recording

4.4. Endoscopy analysis

For each of the patients, the nearest endoscopy report to the fluoromanometry date was collected from the patients’ medical records. Each was graded by the same consultant general surgeon using the following grading score (Table 2). It is important to note that in the final analysis ‘normal’ (N) was compared with ‘not normal’ (NE, E and B). Those with strictures were excluded as it was not known whether they were present before or occurred as a result of oesophagitis. Furthermore, it was noted whether the patients were on/off medication at the times of the different investigations. This was carried out by reading through the notes as this information is not recorded directly on the endoscopy reports.

<table>
<thead>
<tr>
<th>Grade</th>
<th>Definition (corresponding to oesophagitis grading score)</th>
</tr>
</thead>
<tbody>
<tr>
<td>N</td>
<td>Normal</td>
</tr>
<tr>
<td>NE</td>
<td>Non-erosive (0,1)</td>
</tr>
<tr>
<td>E</td>
<td>Erosive (2,3,4)</td>
</tr>
<tr>
<td>S</td>
<td>Stricture</td>
</tr>
<tr>
<td>B</td>
<td>Barrett's</td>
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</tbody>
</table>

Table 2. Oesophagitis grade
4.5. Data analysis

All the data was entered into a spreadsheet and checked for normality using the Kolmogorov-Smirnov test. The unpaired Student’s t-test that assumes normal distribution was used to compare the means between groups of data, as appropriate. A regression analysis was carried out together with an F test (Graphpad Instat®) that calculates whether the slope is significantly different from zero. To compare the relationship between categorical variables the Fisher’s Exact test was carried out.

5. Results

5.1. Comparison between GORD and Dysphagia

5.1.1. Age and Maximum Lumen Diameter

Patients presenting with a preliminary diagnosis of GORD, Maximum Lumen Diameter increased significantly with Age. (Figure 6 and 7)

![Graph showing Age vs. Maximum Lumen Diameter](GORD age vs. MLD)

Figure 6. Age vs. Maximum Lumen Diameter (GORD)
Patients presenting with a preliminary diagnosis of Dysphagia, *Maximum Lumen Diameter* increased with *Age* but was not statistically significant at the 5% level. (Figure 8)
Combining the GORD and Dysphagia group, Maximum Lumen Diameter increased significantly with Age. (Figure 9 and 10)

Figure 9. Age vs. Maximum Lumen Diameter (GORD and Dysphagia)

Figure 10. Age vs. Maximum Lumen Diameter at P4 (GORD and Dysphagia)
In those with a preliminary diagnosis of GORD and having endoscopically diagnosed Oesophagitis there was improved correlation between Age and Maximum Lumen Diameter. (Figure 11)

![Graph showing Age vs. Maximum Lumen Diameter (GORD with confirmed oesophagitis)](image)

**Figure 11.** Age vs. Maximum Lumen Diameter (GORD with confirmed oesophagitis)

### 5.1.2. Dysphagia and Age

Those patients presenting with symptoms of *Dysphagia* are significantly older, mean 58.23 (sd ± 16.42), than patients presenting with a preliminary diagnosis of *GORD*, mean 46.6 (sd ± 12.01), p = 0.0056 (student t test).

### 5.1.3. Maximum Lumen Diameter, 24 hour pH monitoring

No significant difference in *Maximum Lumen Diameter* and parameters of *24 hour pH monitoring* between the GORD and Dysphagia populations.
5.1.4. Preliminary diagnosis and Oesophagitis

36% (9/25) patients with a preliminary diagnosis of GORD had Oesophagitis.

18.75% (3/16) patients with a preliminary diagnosis of Dysphagia had Oesophagitis.

5.2. Comparison between patients with and without Hiatus Hernia

5.2.1. 24 hour pH monitoring

No significant difference between the parameters of 24 hour pH monitoring was found, for patients with and without Hiatus Hernia diagnosed by radiology or endoscopy.

5.2.2. Maximum Lumen Diameter

There was a small difference in Maximum Lumen Diameter noted between the two groups at the level of the P4 sensor, p=0.077 (student t test).

5.3. Comparison of patients with and without Symptoms Corresponding to pH events

5.3.1. 24 hour pH monitoring

Parameters of 24 hour pH monitoring were compared between patients with and without Symptoms Corresponding to pH events. A statistically significant difference was detected for the following parameters:

- Total percentage time pH<4  p=0.0005
- Percentage upright reflux  p=0.0007
- No. of upright reflux episodes p=0.00003
- Percentage supine reflux  p=0.017
- No. of supine reflux episodes  p=0.001  (student t test)
5.3.2. Maximum Lumen Diameter, Diameter at P4

No statistical differences in Maximum Lumen Diameter or Diameter at P4 were detected.

5.3.3. Hiatus Hernia

63% (12/19) of patients with Symptoms Corresponding to reflux episodes had a Hiatus Hernia, compared to 44.8% (13/29) with No Symptoms Corresponding. This was not significant, p=0.25 (Fisher’s Exact test).

5.3.4. Oesophagitis

35.7% (5/14 recorded) had Oesophagitis in the Symptoms Corresponding group compared to 26.1% (6/23) in the No Symptoms Corresponding group. This was not significant, p=0.71 (Fisher’s Exact test).

5.4. Comparison between patients with and without Pathological Reflux

5.4.1. Estimated Clearance

Investigation of the relationship between Estimated Clearance assessed at radiology and patients with and without Pathological Reflux i.e. total exposure time > 6% showed:

Estimated Clearance was found to be reduced from 87.36% (sd ± 5.6%) to 79.75% (sd ± 8.16%) in patients with Pathological Reflux, p=0.0006 (student t test).

5.4.2. Diameter at P4

A slight difference in Lumen Diameter at P4 with Pathological Reflux mean 1.5cm (sd ± 0.32) and without Pathological Reflux mean 1.68cm (sd ± 0.33), p= 0.065 (student t test).
5.5. **Subpopulation of patients with Pathological Reflux**

In patients with Pathological Reflux, Estimated Clearance is statistically greater in patients with HH mean 82.8% (sd ± 5.35%) than in patients without a HH mean 76% (sd ± 9.67), p=0.029 (student t test).

5.6. **Comparison between patients with and without Oesophagitis**

5.6.1. **Maximum Lumen Diameter**

There was a small difference observed between Maximum Lumen Diameter with Oesophagitis mean 2.03cm (sd ± 0.28) and without Oesophagitis mean 1.85cm (sd ± 0.36), p=0.124 (student t test).

5.6.2. **Hiatus Hernia**

83.33% (10/12) of Oesophagitis patients had a Hiatus Hernia. Of those with No Oesophagitis 51.8% (14/27) had a Hiatus Hernia. This was considered not quite significant, p=0.08 (Fisher’s Exact test).

5.6.3. **24 hour pH monitoring**

There were no differences between the pH parameters measured, in those with and without Oesophagitis.

5.6.4. **Estimated Clearance**

No significant difference in estimated clearance between the two groups.

5.7. **Combining Time exposed (%time pH<4) and Maximum Lumen Diameter**

In all statistical investigations combining Time exposed and Maximum Lumen Diameter showed no significant difference.
6. **Discussion**

The main results transpiring from this study are:

1. (a) For those patients presenting with a preliminary diagnosis of GORD and dysphagia, both the lumen diameter measured at its maximum and the diameter measured at the level of the P4 transducer increased with patient age.

   (b) For those patients with oesophagitis presenting with a preliminary diagnosis of GORD, this relation was seen to be stronger.

2. Those patients presenting with symptoms of dysphagia are significantly older than patients presenting with a preliminary diagnosis of GORD.

3. There is a greater probability of oesophagitis if the preliminary diagnosis is GORD than if it was dysphagia, although not statistically significant with the Fisher’s Exact test.

4. The presence of a HH did not significantly affect results obtained from 24 hour pH monitoring. In addition there is no difference in 24 hour pH monitoring results for patients with and without oesophagitis.

5. There is a greater probability of a HH being present than oesophagitis, when there is symptom correlation with 24 hour pH monitoring.

6. Estimated clearance is reduced in patients with pathological reflux. In addition of those with pathological reflux, estimated clearance is statistically greater in patients with HH than without.

7. There is a greater probability of oesophagitis patients having a HH than patients without oesophagitis.
8. There is no difference in 24 hour pH monitoring results for patients with and without oesophagitis.

6.1. Relationship between Age and Diameter

We found that of those patients presenting for investigation with a preliminary diagnosis of GORD, age was significantly related to maximum oesophageal lumen diameter. Hence, the older the patient was the larger the lumen diameter, and this was especially true around the P4 transducer (approximately 3cm from the LOS). The only other study known that considered lumen diameter with age in GORD patients, did not find a good relationship between the variables. However, they selected and grouped patients with a number of upper ‘aerodigestive symptoms’. Interestingly, from our study, the relationship between age and lumen diameter is stronger in the GORD patients, and even though still significant is less well correlated when we combined the GORD and dysphagia group.

Graziani et al.(1983) sampled a control group of 164 patients without oesophageal reflux and reflux oesophagitis (i.e. normal) and found that their diameters were virtually uninfluenced by age or sex. Thus it seems that normally the diameter of the oesophagus is not affected by age but under the influence of a pathological disease an association is established. It might be possible that as a sequela of GORD the walls of the mucosa become weakened and dilated thus predisposing to further reflux and damage. Furthermore reduced LOS tone, a factor involved in the pathophysiology of GORD, may result in increased lumen diameter. Interestingly, a reduction in the density of muscle fibres per unit area have been detected in the distal oesophagus with ageing and this might be contributing in some way.

Patients who go on to develop GORD may have some unknown predisposition of the oesophagus, which is being reflected in our study by increasing lumen diameter with age. Moreover, amongst those patients with a preliminary diagnosis of GORD, in which the diagnosis of oesophagitis had been confirmed endoscopically, there was a stronger relationship between age and diameter. Thus this appears to support the importance of pathology when considering age and oesophageal lumen diameter.

Finding a significant change in the structure of the oesophagus with ageing, supports the controversial topic of presbyoesophagus. It is important, however, to be
aware that unknown factors could play a role and thus correlation may not imply causation.

6.2. **Dysphagia subpopulation and Age**

In our study, patients presenting with a preliminary diagnosis of dysphagia were significantly older. This corroborates previous findings of a higher incidence of dysphagia in the elderly population. Most elderly patients have functional type dysphagia, i.e. resulting from diseases such as scleroderma and Parkinson’s, which occur more frequently in older people. Further information could have been extrapolated from our findings if diseases such as those mentioned above were noted from the patients records.

6.3. **Maximum Lumen Diameter and Oesophagitis**

Comparison of those patients with and without oesophagitis, did not give a statistically significant difference in the maximum lumen diameters (p=0.124), although patients with oesophagitis had on average a wider lumen diameter.

However, Chen *et al.* and Graziani *et al.* both found statistical significance with oesophageal diameter and oesophagitis. The clinical evidence shows that a collapsed or narrow lumen diameter results in oesophageal mucosal folding (Figure 3). In addition, the areas of erythema at the tips of the folds have been shown to correspond to acid/peptic damage. This suggests that area of mucosa exposed to luminal acid content is variable. The larger the diameter of the oesophagus, the fewer the number of mucosal folds, and therefore extended acid exposure proportional to the radius. There will also be reduced protective effect of the mucosal secretions hence leading to increased probability of developing oesophagitis. In contrast, the smaller the diameter, i.e. the more collapsed the oesophagus, the greater the mucosal folding and thus minimal acid exposure.

Possible reasons why we did not find any difference in lumen diameter between the two groups could be attributed to the small number of patients diagnosed with oesophagitis in this study. Thus increasing our sample size, and so having a larger population with oesophagitis, might enable this difference to be statistically recognised. In addition, the difference between the lumen diameters of oesophagitis
and no oesophagitis was around 2mm, in accordance with the study by Chen et al. Regarding the measurement of the maximum lumen diameter, there was little detail of the measurement techniques used and the volume swallowed in the previous study. This may account for the difference in lumen diameters found between this study and those in the literature.

6.4. Validity of 24 hour pH monitoring

The presence of a HH did not significantly affect the results of 24 hour pH monitoring. Although this method of investigation is considered the ‘gold standard’ and as HH is considered an important factor in the pathogenesis of GORD, reservations arise as to whether 24 hour pH monitoring is providing us with adequate information. Moreover a difference could not be found in 24 hour pH monitoring parameters when comparing those patients with and without a diagnosis of oesophagitis. Thus 24 hour ambulatory pH monitoring may only be giving an approximation of mucosal acid contact and might explain why acid reflux is a poor predictor of severity of erosive reflux oesophagitis.

Significance was found with parameters of the pH investigation, when comparing whether or not symptoms corresponded to pH events. This demonstrates that 24 hour pH monitoring is telling some of the story, although not necessarily painting the full picture.

6.5. Oesophageal Clearance and Pathological Reflux

Estimated clearance was found to be reduced in patients with pathological reflux. This is widely accepted as it is known that oesophageal clearance is an important factor in the pathogenesis of GORD. Our study also noted a slight difference in maximum lumen diameter at P4 between those patients with and without pathological reflux (p=0.065). The diameter was smaller in patients with pathological reflux and may suggest the role of a protective mechanism of the oesophagus to minimise acid exposure. Moreover it might be a sequela of continued acid reflux thus causing anatomical structural changes of the oesophagus.

Surprisingly in those patients with pathological reflux, estimated clearance was significantly greater in those patients with a HH. Although it is generally thought
that HH is a significant factor in GORD pathophysiology, a review of the literature highlights great debate on the matter.\textsuperscript{5} In patients with HH, there was a slight difference although not significant at the 5\% level, in maximum lumen diameter at P4. The diameter was larger in patients with HH and this might be demonstrating the effect of HH on the morphology of the oesophagus. Hence, this study points out that although there may be a relationship between HH and GORD, the mechanisms are complex and are not completely understood.

6.6. Combining Time Exposed and Maximum Lumen Diameter

In all of the parameters investigated, combining time exposed and maximum lumen diameter did not improve our results. An important reason to consider why this may have been the case, is that we were not actually measuring the lumen area as this is not possible. Thus using diameter as an approximation was not strong enough to bring out any difference in our sample population. This might be improved by investigating a larger number of patients but it is important to remember the following: (a) It becomes increasingly difficult to define the edges of the oesophagus once the barium has cleared and in reality it is not possible to know what happens to the diameter of the lumen at that point. Furthermore, (b) the oesophagus is a dynamic structure and the diameter measured is that only of a short period of time, as its morphology is always changing.

6.7. Practical Considerations

6.7.1. Measurement of Diameter

The measurement of lumen diameter was carried out using fluoromanometry. Although the video image of the oesophagus is two dimensional, the oesophagus is a three-dimensional structure. Thus not knowing if the oesophagus had for example become elliptical during the measurement would affect the accuracy of the reading. If the oesophagus was at an angle during the swallow this would also affect the diameter measurement, probably making it slightly larger. There is also an element of human error involved as the area of widest diameter was decided upon by the investigator whilst reviewing the swallow frame by frame. The ruler needs to be calibrated and
hence resulted in a ruler error with each measurement. Efforts were made to keep this error to a minimum and were also recorded for reference (see appendix).

It is important that during each consecutive swallow the radiological intensifier is not moved as this would disrupt the reference points at which the diameters were being measured. However, as this was a retrospective study, this could not be set up in advance and if there was movement of the intensifier then that patient was removed from the final data analysis.

Difficulty occurred at times when locating the pH probes. In some patients a thin transducer had to be used and identifying them on the video image proved problematical. However, as the fluoromanometry synchronously displays the pressure traces, the probes could accurately be identified from first principles.

The pH probes move upwards during the swallow but the probes were electronically identified on screen using markers whilst stationary and thus these positions were used as our reference point.

The patient was asked to swallow 5ml of barium solution. It may have been possible that they swallowed a small amount first then swallowed the rest when asked to do so. Thus effectively doing two swallows a small and then the main swallow. If there was considerable doubt about any particular swallow then it was removed from final analysis. As the patient carries out five swallows it was still possible to calculate an average for the measurements, even if a particular swallow had to be removed. It is important that at least a 30 second time interval is left between each swallow to allow the swallowing reflex to recover.36

6.7.2. Endoscopy

Ideally it is preferred if the endoscopy is carried out close to the date of the fluoromanometry. However, in reality this is not always possible. Clinical decisions are made on results of investigations that can be months apart. Therefore a criterion was set to obtain the closest corresponding endoscopy reports to the fluoromanometry and 24 hour pH monitoring. Those that were excessively far apart were not included in the study.
6.7.3. *pH Investigation*

Data from 24 hour pH monitoring is entered into a database. If some of the data was mistyped then this would again lead to errors in my final results. With some of the patients, missing fields indicated technical errors with that particular study.

6.7.4. *Experimental Populations*

The sample of patients that we investigated had been referred because their symptoms were particularly troublesome and not responding to the conventional treatments. Thus it does not represent the population of GORD, but a population whose symptoms of GORD necessitate referral to tertiary services for more detailed investigations.

6.7.5. *Retrospective study vs. Prospective study*

This was a retrospective study and thus to an extent limited. For example, retrospective studies may have problems such as introducing bias from the investigator and with the collection and availability of data. These problems were kept to a minimum by carefully defining the criteria used. Attempts were made to ensure that bias was not introduced into the measurement of the oesophageal lumen diameter. This was done by minimising the knowledge of the patient details and history at the time of measurement (i.e. the measurement of lumen diameter was carried out blind). Retrospective studies are useful to help define and start understanding clinical issues. However, to further enhance our knowledge about the role played by oesophageal diameter and acid exposure, a prospective study would be beneficial. This would enable us to take a more specific history from the patients, improve our measurements of diameter by working closer with the radiology suite so as to focus into the criteria that needs to be met.

Ideally, endoscopy should be graded at the time of the investigation by the same person using a uniform score for the whole study. The clearance measured in this study was a subjective estimate of clearance. It might be possible to improve the method of clearance estimation by incorporating a computerised method of
assessment. The many advantages offered by a prospective study over that of a retrospective one may improve the accuracy and hence the significance of our data.

7. Conclusion

In conclusion we found that age was significantly linked to increased oesophageal lumen diameter. This highlights the importance of oesophageal morphology when trying to understand the pathophysiology of GORD. This understanding is vital, when making decisions on patient management. We know of no other study that has explored this factor in detail.

This study also highlights the complex interactions that occur between different factors in GORD. It points out real limitations in our ability to investigate this disease, which otherwise have been assumed to be a ‘gold standard’ by many clinicians.

Further research considering the results of this investigation may enhance our understanding of the disease and ultimately affect how patients are managed in the future.

8. Acknowledgements

I would like to thank my supervisors Mr R.F. McCloy and Dr K.R. Haylett for their support with my project. I would like to give special thanks to Mrs P. Vales and the team in the GI Investigations Unit and also Dr S.H. Lee who carried out the radiological investigations.
9. References


10. Shay SS, Eggli D, McDonald C. Gastric emptying of solid food in patients with gastroesophageal reflux. *Gastroenterology*: 1987; 92: [459].


References (figures)

Figure 1. and Figure 2

Figure 3., Figure 4. and Figure 5.

Table 1. Modified from
10. Appendix

10.1 Statistical Analysis Results Tables

<table>
<thead>
<tr>
<th></th>
<th>GORD mean (sd)</th>
<th>Dysphagia mean (sd)</th>
<th>p value (student t)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (years)</td>
<td>46.6 (12.01)</td>
<td>58.2 (16.42)</td>
<td>0.0056</td>
</tr>
<tr>
<td>MLD (cm)</td>
<td>1.937 (0.32)</td>
<td>1.853 (0.37)</td>
<td>0.401</td>
</tr>
<tr>
<td>MLD at P4 (cm)</td>
<td>1.596 (0.32)</td>
<td>1.527 (0.40)</td>
<td>0.499</td>
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</tbody>
</table>

10.1.1 Comparing GORD sample and Dysphagia sample

<table>
<thead>
<tr>
<th></th>
<th>HH mean (sd)</th>
<th>No HH mean (sd)</th>
<th>p value (student t)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (years)</td>
<td>53 (13.15)</td>
<td>47.6 (15.66)</td>
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<tr>
<td>MLD (cm)</td>
<td>1.958 (0.35)</td>
<td>1.857 (0.32)</td>
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<tr>
<td>MLD at P4 (cm)</td>
<td>1.654 (0.37)</td>
<td>1.487 (0.30)</td>
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</table>

10.1.2 Comparing HH with No HH

<table>
<thead>
<tr>
<th></th>
<th>Oesophagitis mean (sd)</th>
<th>No Oesophagitis mean (sd)</th>
<th>p value (student t)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (years)</td>
<td>53.7 (16.53)</td>
<td>48.3 (15.33)</td>
<td>0.327</td>
</tr>
<tr>
<td>MLD (cm)</td>
<td>2.031 (0.28)</td>
<td>1.847 (0.36)</td>
<td>0.124</td>
</tr>
<tr>
<td>MLD at P4 (cm)</td>
<td>1.601 (0.25)</td>
<td>1.553 (0.39)</td>
<td>0.698</td>
</tr>
<tr>
<td>% estimated clearance</td>
<td>81.9 (6.87)</td>
<td>83.2 (9.46)</td>
<td>0.670</td>
</tr>
<tr>
<td>combined time exposed * MLD</td>
<td>15.35 (12.33)</td>
<td>17.28 (22.80)</td>
<td>0.794</td>
</tr>
</tbody>
</table>

10.1.3 Comparing Oesophagitis and No Oesophagitis
Pathological Reflux | No Pathological Reflux | p value (student t)
--- | --- | ---
Age (years) | 47.9 (15.71) | 50.82 (11.09) | 0.459
MLD (cm) | 1.862 (0.34) | 1.963 (0.31) | 0.281
MLD at P4 (cm) | 1.499 (0.32) | 1.677 (0.33) | 0.065
% estimated clearance | 79.8 (8.17) | 87.4 (5.65) | 0.00056

**10.1.4 Comparing Pathological Reflux and No Pathological Reflux**

| Symptoms Corresponding to pH events | No Symptoms Corresponding to pH events | p value (student t)
--- | --- | ---
Age (years) | 48.1 (14.5) | 49.3 (13.33) | 0.759
MLD (cm) | 1.884 (0.38) | 1.924 (0.30) | 0.686
MLD at P4 (cm) | 1.521 (0.37) | 1.621 (0.32) | 0.327
Total % pH<4 (%) | 17.0 (15.98) | 4.8 (5.72) | 0.0005
% upright reflux | 17.7 (16.10) | 5.7 (6.27) | 0.0007
No. upright episodes | 77.8 (43.63) | 29.0 (30.79) | 0.00003
% supine reflux | 14.3 (19.53) | 3.9 (9.14) | 0.017
No. supine reflux episodes | 23.9 (30.23) | 4.2 (5.16) | 0.001

**10.1.5 Comparing Symptoms Corresponding to pH events and No Symptoms Corresponding to pH event**
10.2 Linear Regression Analysis

10.2.1 GORD age vs. MLD

Linear Regression

Number of points = 35

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Best-fit Value</th>
<th>Standard Error</th>
<th>95% confidence interval from</th>
<th>to</th>
</tr>
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<tbody>
<tr>
<td>Slope</td>
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<td>0.003900</td>
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<tr>
<td>Y intercept</td>
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<td>X intercept</td>
<td>-85.727</td>
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</table>

Correlation coefficient (r) = 0.5471. r squared = 0.2993

Standard deviation of residuals from line (Sy.x) = 0.2731

Test: Is the slope significantly different from zero?
The P value is 0.0007, considered extremely significant.

This result was obtained from the following ANOVA table.

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<thead>
<tr>
<th>Source of variation</th>
<th>Degrees of freedom</th>
<th>Sum of squares</th>
<th>Mean square</th>
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<tbody>
<tr>
<td>Linear regression (Model)</td>
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<td>Deviations from linearity (Residual)</td>
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F = 14.096
10.2.2 GORD age vs. MLDP4

Linear Regression

Number of points = 35

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Best-fit Value</th>
<th>Standard Error</th>
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<td>X intercept</td>
<td>-56.889</td>
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Correlation coefficient (r) = 0.5876. $r^2$ squared = 0.3453

Standard deviation of residuals from line (Sy.x) = 0.2589

Test: Is the slope significantly different from zero?

The P value is 0.0002, considered extremely significant.

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<td>Total</td>
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$F = 17.407$
10.2.3 GORD Oesophagitis age vs. MLD

Linear Regression

Number of points = 9

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Correlation coefficient (r) = 0.6674. r squared = 0.4455

Standard deviation of residuals from line (Sy.x) = 0.2293

Test: Is the slope significantly different from zero?

The P value is 0.0495, considered significant.

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</tr>
<tr>
<td>Total</td>
<td>8</td>
<td>0.6636</td>
<td></td>
</tr>
</tbody>
</table>

F = 5.624
10.2.4 Dysphagia age vs. MLD

Linear Regression

Number of points = 17

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Best-fit Value</th>
<th>Standard Error</th>
<th>95% confidence interval from to</th>
</tr>
</thead>
<tbody>
<tr>
<td>Slope</td>
<td>0.004118</td>
<td>0.005744</td>
<td>-0.008121 0.01636</td>
</tr>
<tr>
<td>Y intercept</td>
<td>1.613</td>
<td>0.3468</td>
<td>0.8739 2.352</td>
</tr>
<tr>
<td>X intercept</td>
<td>-391.61</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Correlation coefficient (r) = 0.1820. r squared = 0.03314

Standard deviation of residuals from line (Sy.x) = 0.3772

Test: Is the slope significantly different from zero?
The P value is 0.4844, considered not significant.

This result was obtained from the following ANOVA table.

<table>
<thead>
<tr>
<th>Source of variation</th>
<th>Degrees of freedom</th>
<th>Sum of squares</th>
<th>Mean square</th>
</tr>
</thead>
<tbody>
<tr>
<td>Linear regression (Model)</td>
<td>1</td>
<td>0.07316</td>
<td>0.07316</td>
</tr>
<tr>
<td>Deviations from linearity (Residual)</td>
<td>15</td>
<td>2.134</td>
<td>0.1423</td>
</tr>
<tr>
<td>Total</td>
<td>16</td>
<td>2.207</td>
<td></td>
</tr>
</tbody>
</table>

F = 0.5141
10.2.5 Dysphagia age vs. MLDP4

Linear Regression

Number of points = 17

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Value</th>
<th>Error</th>
<th>from</th>
<th>to</th>
</tr>
</thead>
<tbody>
<tr>
<td>Slope</td>
<td>0.004046</td>
<td>0.006154</td>
<td>-0.009068</td>
<td>0.01716</td>
</tr>
<tr>
<td>Y intercept</td>
<td>1.291</td>
<td>0.3716</td>
<td>0.4995</td>
<td>2.083</td>
</tr>
<tr>
<td>X intercept</td>
<td>-319.14</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Correlation coefficient (r) = 0.1674.  r squared = 0.02801

Standard deviation of residuals from line (Sy.x) = 0.4042

Test: Is the slope significantly different from zero?

The P value is 0.5208, considered not significant.

This result was obtained from the following ANOVA table.

<table>
<thead>
<tr>
<th>Source of variation</th>
<th>Degrees of freedom</th>
<th>Sum of squares</th>
<th>Mean square</th>
</tr>
</thead>
<tbody>
<tr>
<td>Linear regression (Model)</td>
<td>1</td>
<td>0.07062</td>
<td>0.07062</td>
</tr>
<tr>
<td>Deviations from linearity (Residual)</td>
<td>15</td>
<td>2.450</td>
<td>0.1634</td>
</tr>
<tr>
<td>Total</td>
<td>16</td>
<td>2.521</td>
<td></td>
</tr>
</tbody>
</table>

F = 0.4323
10.2.6 Combined (GORD and Dysphagia) age vs. MLD

Linear Regression

Number of points = 52

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Value</th>
<th>Standard Error</th>
<th>95% confidence interval from</th>
<th>to</th>
</tr>
</thead>
<tbody>
<tr>
<td>Slope</td>
<td>0.007273</td>
<td>0.003118</td>
<td>0.001005</td>
<td>0.01354</td>
</tr>
<tr>
<td>Y intercept</td>
<td>1.543</td>
<td>0.1634</td>
<td>1.214</td>
<td>1.872</td>
</tr>
<tr>
<td>X intercept</td>
<td>-212.15</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Correlation coefficient (r) = 0.3133.  \( r^2 \) squared = 0.09817

Standard deviation of residuals from line (Sy.x) = 0.3235

Test: Is the slope significantly different from zero?
The P value is 0.0237, considered significant.

This result was obtained from the following ANOVA table.

<table>
<thead>
<tr>
<th>Source of variation</th>
<th>Degrees of freedom</th>
<th>Sum of squares</th>
<th>Mean square</th>
</tr>
</thead>
<tbody>
<tr>
<td>Linear regression (Model)</td>
<td>1</td>
<td>0.5697</td>
<td>0.5697</td>
</tr>
<tr>
<td>Deviations from linearity (Residual)</td>
<td>50</td>
<td>5.234</td>
<td>0.1047</td>
</tr>
<tr>
<td>Total</td>
<td>51</td>
<td>5.803</td>
<td></td>
</tr>
<tr>
<td>F = 5.443</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
10.2.7 Combined (GORD and Dysphagia) age vs. MLDP4

Linear Regression

Number of points = 52

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Best-fit Value</th>
<th>Standard Error</th>
<th>95% confidence interval from to</th>
</tr>
</thead>
<tbody>
<tr>
<td>Slope</td>
<td>0.007793</td>
<td>0.003138</td>
<td>0.001484 0.01410</td>
</tr>
<tr>
<td>Y intercept</td>
<td>1.181</td>
<td>0.1645</td>
<td>0.8501 1.511</td>
</tr>
<tr>
<td>X intercept</td>
<td>-151.53</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Correlation coefficient (r) = 0.3314.  r squared = 0.1098

Standard deviation of residuals from line (Sy.x) = 0.3256

Test: Is the slope significantly different from zero?

The P value is 0.0164, considered significant.

This result was obtained from the following ANOVA table.

<table>
<thead>
<tr>
<th>Source of variation</th>
<th>Degrees of freedom</th>
<th>Sum of squares</th>
<th>Mean square</th>
</tr>
</thead>
<tbody>
<tr>
<td>Linear regression (Model)</td>
<td>1</td>
<td>0.6539</td>
<td>0.6539</td>
</tr>
<tr>
<td>Deviations from linearity (Residual)</td>
<td>50</td>
<td>5.302</td>
<td>0.1060</td>
</tr>
<tr>
<td>Total</td>
<td>51</td>
<td>5.956</td>
<td></td>
</tr>
</tbody>
</table>

F = 6.167
10.3 Fisher's Exact test

10.3.1 Oesophagitis: No Oesophagitis \ HH: NoHH

Fisher's Exact Test

The two-sided P value is 0.0832, considered not quite significant.

The row/column association is not statistically significant.

Relative Risk
Relative risk = 1.607
95% Confidence Interval: 1.032 to 2.503
(using the approximation of Katz.)

Difference between the two proportions
Top row (Oesophagitis):
   Fraction in the left column: 0.8333
Bottom row (NoOesophagitis):
   Fraction in the left column: 0.5185
   95% Confidence Interval of that fraction: 0.3196 to 0.7137
Difference:
   Difference between the fractions: 0.3148

The standard error and the confidence interval of the difference between
proportions can only be calculated when each cell is greater than
five.

Data analyzed

<table>
<thead>
<tr>
<th></th>
<th>HH</th>
<th>NoHH</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Oesophagitis</td>
<td>10</td>
<td>2</td>
<td>12</td>
</tr>
<tr>
<td></td>
<td>(26%)</td>
<td>(5%)</td>
<td>(31%)</td>
</tr>
<tr>
<td>NoOesophagitis</td>
<td>14</td>
<td>13</td>
<td>27</td>
</tr>
<tr>
<td></td>
<td>(36%)</td>
<td>(33%)</td>
<td>(69%)</td>
</tr>
<tr>
<td>Total</td>
<td>24</td>
<td>15</td>
<td>39</td>
</tr>
<tr>
<td></td>
<td>(62%)</td>
<td>(38%)</td>
<td>(100%)</td>
</tr>
</tbody>
</table>
### 10.3.2 HH:noHH \ Symptoms Corresponding:No Symptoms Corresponding

**Fisher's Exact Test**

The two-sided P value is 0.2500, considered not significant.

The row/column association is not statistically significant.

**Relative Risk**

Relative risk = 1.409  
95% Confidence Interval: 0.8291 to 2.394  
(using the approximation of Katz.)

**Difference between the two proportions**

Top row (symcor):
- Fraction in the left column: 0.6316  
  95% Confidence Interval of that fraction: 0.3836 to 0.8372

Bottom row (nosymcor):
- Fraction in the left column: 0.4483  
  95% Confidence Interval of that fraction: 0.2643 to 0.6430

**Difference:**
- Difference between the fractions: 0.1833  
- Standard error of the difference: 0.1474  
- 95% confidence interval of difference: -0.1058 to 0.4724

**Data analyzed**

<table>
<thead>
<tr>
<th></th>
<th>hh</th>
<th>nohh</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>symcor</td>
<td>12</td>
<td>7</td>
<td>19</td>
</tr>
<tr>
<td></td>
<td>(25%)</td>
<td>(15%)</td>
<td>(40%)</td>
</tr>
<tr>
<td>nosymcor</td>
<td>13</td>
<td>16</td>
<td>29</td>
</tr>
<tr>
<td></td>
<td>(27%)</td>
<td>(33%)</td>
<td>(60%)</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td>25</td>
<td>23</td>
<td>48</td>
</tr>
<tr>
<td></td>
<td>(52%)</td>
<td>(48%)</td>
<td>(100%)</td>
</tr>
</tbody>
</table>
10.3.3 Oesophagitis: No Oesophagitis \ Symptom Corresponding: No Symptom Corresponding

Fisher's Exact Test

The two-sided P value is 0.7130, considered not significant.

The row/column association is not statistically significant.

Relative Risk
Relative risk = 1.369
95% Confidence Interval: 0.5119 to 3.661
(using the approximation of Katz.)

Difference between the two proportions
Top row (SymCor):
  Fraction in the left column: 0.3571
Bottom row (NoSymCor):
  Fraction in the left column: 0.2609
  95% Confidence Interval of that fraction: 0.1023 to 0.4839
Difference:
  Difference between the fractions: 0.09627

The standard error and the confidence interval of the difference between proportions can only be calculated when each cell is greater than five.

Data analyzed

<table>
<thead>
<tr>
<th></th>
<th>Oesophagitis</th>
<th>NoOesophagitis</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>SymCor</td>
<td>5</td>
<td>9</td>
<td>14</td>
</tr>
<tr>
<td></td>
<td>(14%)</td>
<td>(24%)</td>
<td>(38%)</td>
</tr>
<tr>
<td>NoSymCor</td>
<td>6</td>
<td>17</td>
<td>23</td>
</tr>
<tr>
<td></td>
<td>(16%)</td>
<td>(46%)</td>
<td>(62%)</td>
</tr>
<tr>
<td>Total</td>
<td>11</td>
<td>26</td>
<td>37</td>
</tr>
<tr>
<td></td>
<td>(30%)</td>
<td>(70%)</td>
<td>(100%)</td>
</tr>
</tbody>
</table>
10.4 Ruler Calibration Error

The average error as a result of uncertainty of measurement using the ruler in the distal region (i.e. probe c to probe d), including GORD and Dysphagia measurements, was 0.028cm. With respect to the difference in lumen diameter measured between those with and without oesophagitis (2.03cm and 1.85cm respectively) this represents an uncertainty of 15%.

10.4.1 GORD

<table>
<thead>
<tr>
<th>probe $a$ – probe $b$ (cm)</th>
<th>probe $c$ – probe $d$ (cm)</th>
</tr>
</thead>
<tbody>
<tr>
<td>-0.387</td>
<td>-0.163</td>
</tr>
<tr>
<td>0.069</td>
<td>-0.014</td>
</tr>
<tr>
<td>-0.199</td>
<td>-0.457</td>
</tr>
<tr>
<td>-0.382</td>
<td>-0.105</td>
</tr>
<tr>
<td>0.056</td>
<td>0.348</td>
</tr>
<tr>
<td>-0.011</td>
<td>0.020</td>
</tr>
<tr>
<td>0.146</td>
<td>0.354</td>
</tr>
<tr>
<td>-0.165</td>
<td>-0.017</td>
</tr>
<tr>
<td>0.298</td>
<td>0.283</td>
</tr>
<tr>
<td>0.412</td>
<td>-0.142</td>
</tr>
<tr>
<td>0.253</td>
<td>0.076</td>
</tr>
<tr>
<td>-0.16</td>
<td>-0.08</td>
</tr>
<tr>
<td>0.094</td>
<td>-0.012</td>
</tr>
<tr>
<td>-0.022</td>
<td>0.071</td>
</tr>
<tr>
<td>0.495</td>
<td>0.019</td>
</tr>
<tr>
<td>0.370</td>
<td>0.466</td>
</tr>
<tr>
<td>0.128</td>
<td>0.124</td>
</tr>
<tr>
<td>-0.43</td>
<td>-0.156</td>
</tr>
<tr>
<td>-0.096</td>
<td>0.401</td>
</tr>
<tr>
<td>0.521</td>
<td>0.197</td>
</tr>
<tr>
<td>0.297</td>
<td>0.191</td>
</tr>
<tr>
<td>-0.002</td>
<td>-0.071</td>
</tr>
<tr>
<td>0.18</td>
<td>-0.145</td>
</tr>
<tr>
<td>0.187</td>
<td>-0.161</td>
</tr>
<tr>
<td>0.101</td>
<td>-0.198</td>
</tr>
<tr>
<td>0.047</td>
<td>0.361</td>
</tr>
<tr>
<td>0.235</td>
<td>-0.477</td>
</tr>
<tr>
<td>-0.258</td>
<td>-0.479</td>
</tr>
<tr>
<td>0.118</td>
<td>-0.249</td>
</tr>
<tr>
<td>0.158</td>
<td>-0.416</td>
</tr>
<tr>
<td>0.144</td>
<td></td>
</tr>
<tr>
<td>-0.361</td>
<td>-0.373</td>
</tr>
<tr>
<td>0.282</td>
<td>-0.057</td>
</tr>
<tr>
<td>0.196</td>
<td>-0.45</td>
</tr>
<tr>
<td>0.407</td>
<td>-0.023</td>
</tr>
</tbody>
</table>

Average=0.0777               Average= -0.039
10.4.2 Dysphagia

<table>
<thead>
<tr>
<th>probe a – probe b (cm)</th>
<th>probe c – probe d (cm)</th>
</tr>
</thead>
<tbody>
<tr>
<td>0.305</td>
<td>-0.447</td>
</tr>
<tr>
<td>0.066</td>
<td>0.380</td>
</tr>
<tr>
<td>-0.462</td>
<td>-0.227</td>
</tr>
<tr>
<td>0.188</td>
<td>0.259</td>
</tr>
<tr>
<td>0.056</td>
<td>0.094</td>
</tr>
<tr>
<td>0.127</td>
<td>0.211</td>
</tr>
<tr>
<td>0.349</td>
<td>-0.003</td>
</tr>
<tr>
<td>0.080</td>
<td>-0.151</td>
</tr>
<tr>
<td>-0.184</td>
<td>-0.154</td>
</tr>
<tr>
<td>-0.017</td>
<td>-0.147</td>
</tr>
<tr>
<td>0.434</td>
<td>0.157</td>
</tr>
<tr>
<td>0.189</td>
<td>0.438</td>
</tr>
<tr>
<td>-0.059</td>
<td>0.191</td>
</tr>
<tr>
<td>0.004</td>
<td>-0.479</td>
</tr>
<tr>
<td>0.068</td>
<td>0.068</td>
</tr>
<tr>
<td>0.353</td>
<td>-0.139</td>
</tr>
</tbody>
</table>

Average=0.094          Average=0.0063
10.5 Proforma

10.5.1 Lumen diameter proforma

Oesophageal Lumen Diameter Study

Hospital Number ___________ Filename ___________

Transducer spacing ___________

Transducer details _________________________

Erect position

<table>
<thead>
<tr>
<th></th>
<th>Swallow 1</th>
<th>Swallow 2</th>
<th>Swallow 3</th>
<th>Swallow 4</th>
<th>Swallow 5</th>
</tr>
</thead>
<tbody>
<tr>
<td>P1</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>P2</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>P3</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>P4</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Largest width</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

% (Estimate) Clearance

Comments and notes

_____________________________________________________________________
_____________________________________________________________________
_____________________________________________________________________

Ruler Error

Calibrated between _____ and ______

Distance between _____ and ______ = ______

Distance between _____ and ______ = ______

Distances recorded in cm to 3dp
Endoscopy Results

Patient Name  ______________
Hospital Number  ______________
Sex  ______________
Weight  ______________
Height  ______________
Medication On / Off  Notes:  ______________________________
Symptoms  Heartburn [ ]  Dysphagia [ ]  Regurgitation [ ]
Other  ___________________________________________________

HH [ ] r/e/m  SHH [ ] r/e/m  None [ ]  Not mentioned [ ]

*r = radiology  e = endoscopy  m = manometry

Grade

______________________________

Notes

___________________________________________________________________
___________________________________________________________________
___________________________________________________________________
___________________________________________________________________
___________________________________________________________________
___________________________________________________________________
___________________________________________________________________
___________________________________________________________________