Is it asthma? Is it reflux?

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University of Hull
a.h.morice@hull.ac.uk
Asthma and PPIs

The NEW ENGLAND JOURNAL of MEDICINE

Efficacy of Esomeprazole for Treatment of Poorly Controlled Asthma

The American Lung Association Asthma Clinical Research Centers

ABSTRACT

BACKGROUND
Gastroesophageal reflux is common among patients with asthma but often causes only minor symptoms. It remains unclear whether esomeprazole suppresses the acid component of gastroesophageal reflux, improving asthma control.

METHODS
In a parallel-group, double-blind trial, we randomly assigned 412 participants with inadequately controlled asthma, despite treatment with inhaled corticosteroids, and with minimal or no symptoms of gastroesophageal reflux to receive either esomeprazole or placebo once daily at bedtime. Participants were followed for 74 weeks with the use of daily diaries, questionnaires, periodic physical examination, and endoscopy. This article is a summary of the trial and its results.

RESULTS
Efficacy of esomeprazole was no different from that of placebo in patients treated as shown in the table of results. In addition, the effect of esomeprazole was no different from that of placebo in patients with asthma.

CONCLUSIONS
Efficacy of esomeprazole was no different from that of placebo in patients treated as shown in the table of results.
Is it asthma? Is it GORD?

No!
Is it asthma? Is it GORD?

No!

but...
Definitions

The chief merit of language is clearness, and we know that nothing detracts from this so much as unfamiliar terms

Galen
British Guideline on the Management of Asthma
A national clinical guideline

May 2008
revised May 2011
2 Diagnosis

The diagnosis of asthma is a clinical one; there is no standardised definition of the type, severity or frequency of symptoms, nor of the findings on investigation. The absence of a gold standard definition means that it is not possible to make clear evidence based recommendations on how to make a diagnosis of asthma.

Central to all definitions is the presence of symptoms (more than one of wheeze, breathlessness, chest tightness, cough) and of variable airflow obstruction. More recent descriptions of asthma in children and in adults have included airway hyper-responsiveness and airway inflammation as components of the disease. How these features relate to each other, how they are best measured and how they contribute to the clinical manifestations of asthma, remains unclear.
## 20th Century Cough Studies

<table>
<thead>
<tr>
<th>Author</th>
<th>Mean age in years</th>
<th>Nº of patients (Nº Female)</th>
<th>Improved</th>
<th>Diagnosis (% of total)</th>
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<tbody>
<tr>
<td>Irwin et al 1981</td>
<td>50.3</td>
<td>49 (27)</td>
<td>98 %</td>
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<td>Poe et al 1982</td>
<td>-</td>
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<td>Poe et al 1989</td>
<td>44.8</td>
<td>139 (84)</td>
<td>88 %</td>
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<tr>
<td>Irwin et al 1990</td>
<td>51</td>
<td>102 (59)</td>
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<td>Hoffstein et al 1994</td>
<td>47</td>
<td>228 (139)</td>
<td>91 %</td>
<td>25</td>
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<td>O’Connell et al 1994</td>
<td>49</td>
<td>87 (63)</td>
<td>68 %</td>
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<td>Smyrnios et al 1995</td>
<td>58</td>
<td>71 (32)</td>
<td>97 %</td>
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<td>Mello et al 1996</td>
<td>53.1</td>
<td>88 (64)</td>
<td>98 %</td>
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<td>Marchesani et al 1998</td>
<td>51</td>
<td>92 (72)</td>
<td>91 %</td>
<td>14</td>
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<tr>
<td>McGarvey et al 1998</td>
<td>47.5</td>
<td>43 (29)</td>
<td>82 %</td>
<td>23</td>
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<tr>
<td>Palombini et al 1999</td>
<td>57</td>
<td>78 (51)</td>
<td>-</td>
<td>59</td>
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<tr>
<td>Brightling et al 1999</td>
<td>-</td>
<td>91 (-)</td>
<td>93 %</td>
<td>31</td>
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</tbody>
</table>
The problems of definition in cough diagnosis

- The asthma syndromes

<table>
<thead>
<tr>
<th>Diagnosis</th>
<th>PEFR variability</th>
<th>Hyper-responsiveness</th>
<th>Sputum eosinophils</th>
</tr>
</thead>
<tbody>
<tr>
<td>Asthma</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>Cough predominant asthma</td>
<td>x</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>Eosinophilic bronchitis</td>
<td>x</td>
<td>x</td>
<td>✓</td>
</tr>
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</table>
The problems of definition in cough diagnosis

- The asthma syndromes
- PNDS/UACS

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<tr>
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<td>✓</td>
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<td>✓</td>
</tr>
<tr>
<td>Cough predominant asthma</td>
<td>×</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>Eosinophilic bronchitis</td>
<td>×</td>
<td>×</td>
<td>✓</td>
</tr>
</tbody>
</table>

Post-nasal drip syndrome—a symptom to be sniffed at?

Alyn H. Morice*

*University of Hull, Castle Hill Hospital, Castle Road, Cottingham, East Yorkshire HU16 5JQ, UK
The problems of definition in cough diagnosis

- The asthma syndromes
- PNDS/UACS
- GERD/GORD

<table>
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<tr>
<th>Diagnosis</th>
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<tr>
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<td>×</td>
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</table>

Post-nasal drip syndrome—a symptom to be sniffed at?

Alyn H. Morice*

University of Hull, Castle Hill Hospital, Castle Road, Cottingham, East Yorkshire, UK
Up regulation of the cough reflex

Morice AM et al
Lancet 1987;1116
Effect of viral upper respiratory tract infection on the urge-to-cough sensation

Peter V. Dicpinigaitis*, Rajani Bhat, William A. Rhoton, Amit S. Tibb, Abdissa Negassa

Respiratory Medicine (2011) 105, 615–618
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Respiratory Medicine (2011) 105, 615–618

Original article

Sensitivity to methacholine and capsaicin in patients with unclear respiratory symptoms

Background: Capsaicin, the pungent ingredient in red pepper, is known to stimulate coughing via the sensory nervous system. Earlier studies showed that patients with airway symptoms induced by chemicals and strong scents cough more after inhalation of capsaicin than healthy control subjects and this has been interpreted as a hyperreactivity of airway sensory nerves. Our aim was to study airway sensitivity to inhaled capsaicin and the occurrence of airway symptoms induced by strong scents in patients who underwent a bronchial methacholine test, primarily because of suspected asthma.

Methods: Fifty-two consecutive patients referred for testing with methacholine were also provoked with inhaled capsaicin in increasing concentrations. Cough sensitivity to capsaicin was compared with that in 40 healthy control subjects.

Results: The patients coughed significantly more compared with the healthy control subjects with each dose of capsaicin (P<0.0001). Twelve patients (23%) had a positive methacholine test, and of these, nine were diagnosed with asthma. There was no difference in capsaicin sensitivity between patients sensitive or insensitive to methacholine.

Conclusions: The majority of the patients had no increased sensitivity to methacholine but did demonstrate sensory hyperreactivity (SHR). SHR appears to be a common diagnosis in investigations of patients with obscure airway symptoms.
The Chilli pepper

Pepe d’India

J Discolli del Ma Hiali
Venezia 1569

A kind gift from Dr Amy Kantar
The TRP (Transient Receptor Potential) Family

**HOT**
- 55°C: TRPV2
- 43°C: TRPV1
- 33°C: TRPV3
- 30°C: TRPV4
- 25°C: TRPM8
- 17°C: TRPA1

**COLD**
- VRL1
- VR1: capsaicin, protons
- VRL3
- VR-OAC, OTRPC4: osmotic
- CMR1: cold/menthol
- Coexpressed with VR1

*Cell 2003 112:819-829*
Chronic cough is the disease. The body responds in different ways to the precipitant.

But what causes the irritation in chronic cough?
The Cough Hypersensitivity Syndrome: single clinical entity

Chronic cough is the disease. The body responds in different ways to the precipitant.

But what causes the irritation in chronic cough?

Airway reflux
Airway Reflux causing cough is

- Not the same as reflux causing heartburn (GOR)
- Not necessarily acidic
- Frequently gaseous
- Episodic
- Can be of short duration
- Able to reach the larynx, nose, lungs, and ears
- What better precipitant of a TH2 response?
"snowing"
as consequence
of the gas pressure
and the body movement
Comparative anatomy

- Pilot Whale
- Deer
- Cat
- Spider Monkey

AHM 2007

Laitinen and Reidenberg Am J Med 1997
Human anatomy

- Larynx and associated structures descend
- Epiglottis and soft palate no longer in contact
- Tongue forms anterior pharyngeal wall
- Greatly expanded oropharynx
Reflux Airway Disease

Daisy cells stained with ORO and Haematoxylin
Daisy cells incubated with 10% v/v Calogen for 24h at 37°C
Reflux Airway Disease

- IL-4, IL-5, IL-10, IL-12
- IFNγ, IL-8
- IL-1, TNFα, NGF

- Eosinophilic Infiltration
- Neutrophilic Infiltration
- TRP channel Up-regulation
Within the last MONTH, how did the following problems affect you?

0 = no problem and 5 = severe/frequent problem

<table>
<thead>
<tr>
<th>problem</th>
<th>0</th>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
<th>5</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hoarseness or a problem with your voice</td>
<td></td>
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<tr>
<td>Clearing your throat</td>
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<tr>
<td>Excess mucus in the throat, or drip down the back of your nose</td>
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<tr>
<td>Retching or vomiting when you cough</td>
<td></td>
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<tr>
<td>Cough on first lying down or bending over</td>
<td></td>
<td></td>
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<td></td>
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<tr>
<td>Chest tightness or wheeze when coughing</td>
<td></td>
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</tr>
<tr>
<td>Heartburn, indigestion, stomach acid coming up (or do you take medications for this, if yes score 5)</td>
<td></td>
<td></td>
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<tr>
<td>A tickle in your throat, or a lump in your throat</td>
<td></td>
<td></td>
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<tr>
<td>Cough with eating (during or straight after meals)</td>
<td></td>
<td></td>
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<tr>
<td>Cough with certain foods</td>
<td></td>
<td></td>
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<tr>
<td>Cough when you get out of bed in the morning</td>
<td></td>
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<tr>
<td>Cough brought on by singing or speaking (for example, on the telephone)</td>
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<tr>
<td>Coughing during the day rather than night</td>
<td></td>
<td></td>
<td></td>
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<td></td>
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</tr>
<tr>
<td>A strange taste in your mouth</td>
<td></td>
<td></td>
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</tbody>
</table>

TOTAL SCORE____________________ /70
Airway reflux causes cough

(and most other chest disease)
Is it asthma? Is it reflux?

George Congreve
"On Consumption of the Lungs" 1881

refer him to the case of Lady B——, reported hereafter.

There is also a dry or nervous asthma, with little or no expectoration, accompanied with flatulence, headache, restlessness, dryness of throat, and intense anxiety. In most cases of this class, dyspepsia is an accompanying evil, and perhaps the exciting cause. In addition to the medicinal agents above named, the proper regulation of diet is of vast importance. Nothing to generate flatulence should be taken. The food should be light and nourishing—no pastry, salt meat, veal, pork, hashes, soups, or stews—but mutton, tender beef (underdone), stale bread, very little vegetable, and light puddings. A very small quantity of best brandy, well diluted and without sugar, or with half a tumblerful of Schweppes’s Potass or Seltzer Water, may be sipped at dinner. During intervals of attack, a course of bitter tonics, such as cascara, columba, or quassia, to give tone to the stomach, may be of much advantage.

I am frequently asked my opinion of the use of inhaling apparatus and medicated inhalation, both in cases of asthma and of phthisis. Attempts from time to time have been made to revive this old and exploded system. It has been tried over and over again, and signal failure. In many cases injudicious inhaling has caused decided injury. In no case have I known the practice of inhalation productive of any permanent good.
They have reflux but only a few have acid reflux

- Acid does not cause this disease
- PPIs do NOT work (more than placebo) except in severe heartburn

Mrs JT

- 55 year old oncology nurse
- Developed “late onset asthma” 14 years ago
- Under a colleague who gradually had to increase treatment.
  - Pred 20mg, montelukast, Seretide, theophylline
- Sudden onset of SOB and wheeze.
- Falling FEV1 - ITU admissions
- Second opinion please!
Mrs JT

- Numerous atypical features
- Attacks sudden in onset
- Positional
- Precipitated by drinking (wine)
- Predominant cough between episodes
- HARQ score 57
Airway reflux causes cough
(and pneumonia)
Distribution of cough reflex threshold ($C_5$) assessed by citric acid

Healthy Young Adults
Age=28.8±7.5 yrs
n=57

Nursing Home Residents
Age=84.4±5.6 yrs
n=123

Cough reflex threshold in patients with recurrent aspiration pneumonia

Sekizawa K, Ujiie Y, Itabashi S, Sasaki H, Takishima T
Lack of cough reflex in aspiration pneumonia
Lancet;335:1228-1229, 1990
The swallowing reflex provocation test in human

ATOM tube
(8Fr diameter 2.70mm)

1ml of the distilled water
Swallowing Reflex Sensitivity

Cough Reflex Sensitivity

Healthy Elderly

Elderly patients with repeated aspiration pneumonia

Demented Elderly

Nakagawa H, Sekizawa K, Ujiie Y, Sasaki H, Takishima T
Risk of aspiration pneumonia in the elderly
Chest 1993; 103: 1636-37
Relationship between water temperature and latency of swallowing reflex

Ebihara et al.
*J Am Geriatr Soc* 2004; 52 (12): 2143-4
Effect of temperature on swallowing reflex in elderly patients with aspiration pneumonia.

**Thermoreceptor (TRP channel)**
- TRPM8
- TRPA1
- TRPV3,4
- TRPV2
- TRPV1

**Agonist**
- menthol (mint)
- capsaicin, acid
- allyl-isothiocyanate (wasabi), cinnamaldehyde (cynamon)
Protocol for start oral intake with prevention of re-aspiration in patients with aspiration pneumonia

Fasted

Acute phase
- Aromatherapy by black pepper oil
- Capsaicin troche

Oral intake
- Menthol jelly
- Dysphagia food
- ACE inhibitors
- Amantasin

Oral care

Swallowing rehabilitation

Admission

Discharge

Comparison of incidence of aspiration pneumonia before and after the use of the protocol in the Geriatric Care Unit

<table>
<thead>
<tr>
<th></th>
<th>Control Group (1st admission) N=17</th>
<th>Protocol Group (2nd admission) N=17</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (years old)</td>
<td>80.3 ±7.2</td>
<td>81.2 ±7.0</td>
<td>n.s.</td>
</tr>
<tr>
<td>MMSE (point)</td>
<td>5.2 ±4.8</td>
<td>4.8 ±4.2</td>
<td>n.s.</td>
</tr>
<tr>
<td>Barthel Index</td>
<td>24.3 ±20.6</td>
<td>20.5 ±19.3</td>
<td>n.s.</td>
</tr>
<tr>
<td>Serum Albumin (g/dl)</td>
<td>2.9 ±0.7</td>
<td>2.9 ±0.5</td>
<td>n.s.</td>
</tr>
<tr>
<td>Latency of Swallowing reflex</td>
<td>18.9 ±23.4</td>
<td>20.6 ±23.9</td>
<td>n.s.</td>
</tr>
<tr>
<td>Incidence of re-aspiration pneumonia</td>
<td>16</td>
<td>5</td>
<td>&lt;0.01</td>
</tr>
<tr>
<td>Pyrexia period (days)</td>
<td>6.8 ±4.7</td>
<td>1.3 ±1.7</td>
<td>&lt;0.01</td>
</tr>
</tbody>
</table>
What about COPD?

Asthma (eosinophilic bronchitis)

Emphysema

Chronic Bronchitis (neutrophilic bronchitis)
Chronic bronchitis

British MRC Respiratory Questionnaire

‘Cough and sputum expectoration occurring on most days for at least 3 months of the year and for at least 2 consecutive years when other pulmonary and cardiac causes of the chronic productive cough are excluded’

Oswald N et al. Lancet 1953
COPD patients with productive cough

- More likely to have exacerbations
  Seemungal TA et al. Am J Respir Crit Care Med 98

- More rapid decline in lung function
  Vestbo J 1996, Kanner RA et al. Am J Respir Crit Care Med 01

- More likely to die early
Cough in exacerbations of COPD

24 Hour Cough Pattern (n=9)

Mean coughs per Hour

Day 0
Day 4

Time

00:00 01:00 02:00 03:00 04:00 05:00 06:00 07:00 08:00 09:00 10:00 11:00 12:00 13:00 14:00 15:00 16:00 17:00 18:00 19:00 20:00 21:00 22:00 23:00
Last week in a chest clinic near you

- 69 year old ex hospital cleaner “chronic asthma”
- 40 pack years, FEV1 1.0
- Requesting home O2
- 6 years F/U in chest clinic – COPD + panic disorder
• Severe sudden episodes of SOB with cough
• Loss of voice
• Investigated with angiogram by cardiologists
• Daughter has exactly the same story
• Both scored over 50 on the HARQ
Bronchiectasis?

1819, Laennec:
a chronic, debilitating disease

1932, Warner:
“copious foetid sputum...marked constitutional symptoms...a social outcast...”
Bronchiectasis

- Patients suffer the clinical triad of chronic cough, chronic sputum production and recurrent chest infections.

- Precise prevalence unknown, figures to date suggest 4.2/100 000 aged 18-34 to 271.8/100 000 aged >75yrs
  
  Weycker 2005 Clin Pulm Med

- Prevalence higher among women, 63-68%
  

- Edinburgh- around 620 attend the bronchiectasis clinic.
Exacerbations

- Number of exacerbations needing antibiotic therapy as outpatient was recorded for the year during which the study was conducted.

<table>
<thead>
<tr>
<th>Exacerbations</th>
<th>Reflux positive (n=120)</th>
<th>Reflux negative (n=43)</th>
</tr>
</thead>
<tbody>
<tr>
<td>None</td>
<td>34 (28.3%)</td>
<td>19 (44.1%)</td>
</tr>
<tr>
<td>1-2</td>
<td>46 (38.3%)</td>
<td>20 (46.5%)</td>
</tr>
<tr>
<td>3-5</td>
<td>25 (20.8%)</td>
<td>3 (6.9%)</td>
</tr>
<tr>
<td>&gt; 5</td>
<td>35 (29.1%)</td>
<td>1 (2.3%)</td>
</tr>
</tbody>
</table>
Chronic colonization

- 82 and 19 were chronically colonized in the reflux positive and negative group respectively.

<table>
<thead>
<tr>
<th>Microorganisms</th>
<th>Reflux +ve (n=120)</th>
<th>Reflux –ve (n=43)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Enteric gram -ve</td>
<td>30 (25%)</td>
<td>4 (9.3%)</td>
</tr>
<tr>
<td>Other PPM</td>
<td>70 (58.3%)</td>
<td>20 (46.5%)</td>
</tr>
<tr>
<td>MNF</td>
<td>38 (31.7%)</td>
<td>24 (55.8%)</td>
</tr>
</tbody>
</table>
cystic fibrosis

- Obviously a “lung” disease
- Yet patients suffer from a dry cough
- Investigation shows very high levels of reflux
Drug treatment

- Metaclopramide
- Domperidone
Drug treatment

- Metaclopramide
- Domperidone
- Baclofen
- Azithromycin
- Disafrol
Fundoplication

• Laparoscopic, general anaesthesia, five port.
• Oesophageal hiatus fully dissected and oesophagus mobilised.
• Non absorbable suture to approximate the crura posterior to the oesophagus.
• Calibration of the oesophageal hiatus was clinical, 56 Fr endoluminal bougie available.
### Results: change in VAS score for cough

<p>| | |</p>
<table>
<thead>
<tr>
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</thead>
<tbody>
<tr>
<td><strong>N</strong></td>
<td>47</td>
</tr>
<tr>
<td><strong>Women</strong></td>
<td>36</td>
</tr>
<tr>
<td><strong>Age (Median, Range)</strong></td>
<td>55  (32-79)</td>
</tr>
<tr>
<td><strong>Duration of cough in years (Median, Range)</strong></td>
<td>5.0 (1-30)</td>
</tr>
<tr>
<td><strong>Peptic symptoms present in</strong></td>
<td>85%</td>
</tr>
<tr>
<td><strong>Significant acid reflux present in</strong></td>
<td>72%</td>
</tr>
<tr>
<td><strong>Decreased lower oesophageal sphincter pressure</strong></td>
<td>28%</td>
</tr>
<tr>
<td><strong>Response to treatment</strong></td>
<td>64%</td>
</tr>
<tr>
<td>Complete</td>
<td>45%</td>
</tr>
<tr>
<td>Partial</td>
<td>19%</td>
</tr>
</tbody>
</table>
Effect of Fundoplication on cough and exacerbation in cystic fibrosis

- **Patients**

<table>
<thead>
<tr>
<th>Number of Exacerbation Episodes</th>
<th>Post-LNF</th>
<th>Pre-LNF</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>2</td>
<td>0</td>
</tr>
<tr>
<td>2</td>
<td>4</td>
<td>4</td>
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<td>4</td>
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<td>11</td>
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<tr>
<td>10</td>
<td>12</td>
<td>12</td>
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</table>

- **LCQ (Physical)**

- **LCQ (Psycho)**

- **LCQ (Social)**

- **Total LCQ**

**Graph:**

- **Pre-LNF** vs **Post-LNF**

**Legend:**

- Post-LNF
- Pre-LNF

**Number of Exacerbation Episodes**

- **Patients**

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<th>6</th>
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</table>

**Notes:**

- Cough and exacerbation were reduced post-Fundoplication in cystic fibrosis patients.
- The graph illustrates the number of exacerbation episodes and the change post-LNF.
The obese reflux cough

- Fundoplication will not work because of high pressures
- Abdominal fat is the cause
- A combined bariatric and anti reflux procedure is required
Roux-en-Y

Pre op
- Chest “unbearable”
- BMI 31
- Insulin >200u / day
- 3 anti-hypertensives

2 months post op
- Morning cough only
- BMI 26
- Insulin 80u / day
- BP normal off treatment

“My life has been transformed”
Miss KJ

- Aged 17 (only 1 child)
- Severe intractable “asthma”
  - Prednisolone 20mg
  - Zolair
  - Theophyline etc etc
- Repeated hospital admissions
  - Sudden onset
  - Bronchospasm hypoxic to ITU
  - Rapid recovery, well between episodes
Miss KJ

- Emergency Nissen Fundoplication 1 year ago
- Took own discharge 2 days post op
- A single further admission
- Has not attended for any anti asthma medication
- Visited by asthma nurse – does not want further contact
Miss KJ

- Shortly after last slide prepared
- Found dead in bed
- Ventolin inhaler under pillow
- Classic status asthmaticus at pm