*Summary and conclusions*

# Dyspepsia and Gastro-oesophageal Reflux

## A Systematic Review

The Swedish Council on Technology Assessment in Health Care

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*Summary and Conclusions of the SBU Report:*

# Dyspepsia and Gastro-oesophageal Reflux

## A Systematic Review

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# SBU's Conclusions

## Background

Dyspepsia is a broad term for a range of symptoms – abdominal bloating after eating, early satiety, and pain or burning sensation in the upper gastrointestinal tract – that are assumed to originate from the stomach or duodenum. Dyspepsia is referred to as organic if clinical investigation can trace the symptoms to a demonstrable disease, such as a peptic ulcer or cancer, and functional if it cannot.

Heartburn and acid regurgitation are no longer considered to be symptoms of dyspepsia, but of gastro-oesophageal reflux (the backflow of acid or stomach contents into the oesophagus).

Uninvestigated dyspepsia and uninvestigated reflux symptoms are those that have not been subjected to an oesophago-gastro-duodenoscopy (OGD) or any other diagnostic examinations of the oesophagus, stomach and duodenum. Both the symptoms and underlying causes vary widely. Some patients may have peptic ulcers or oesophagitis (inflammation and superficial ulceration of the oesophagus), while others may have cancer.

## Conclusions

### Uninvestigated Gastro-oesophageal Reflux Symptoms

- ❑ Both proton pump inhibitors (PPIs) and histamine-2 receptor antagonists (H2RAs) are more effective than placebo for relieving gastro-oesophageal reflux symptoms (Evidence Grade 1), and PPIs are more effective than H2RAs (Evidence Grade 1).

- A considerable percentage of patients who are treated for acid gastro-oesophageal reflux symptoms without preceding investigation are satisfied with on-demand PPI therapy or continuous H2RA therapy (Evidence Grade 3).

### Uninvestigated Dyspepsia

- When it comes to relieving symptoms in patients with uninvestigated dyspepsia, no significant differences have been found between diagnosis of Helicobacter pylori *(H. pylori)* bacteria combined with treatment of detected infection and an OGD combined with treatment of detected disorders (Evidence Grade 2). Empirical therapy with acid inhibitors relieves symptoms as effectively as treatment based on an OGD (Evidence Grade 3).

- Both advanced age and the presence of alarm symptoms in dyspepsia – including bleeding, dysphagia (difficulty swallowing) and weight loss – increase the probability of an underlying malignant tumour (Evidence Grade 3). But a considerable percentage of patients with a tumour have no alarm symptoms at their first medical consultation (Evidence Grade 3).

### Functional Dyspepsia

- Acid inhibitors can provide some relief of the symptoms of functional dyspepsia (Evidence Grade 3). But because the evaluated studies sometimes include patients with gastro-oesophageal reflux symptoms, the efficacy of the drugs is difficult to assess.

- Antibiotic therapy that eradicates *H. pylori* eradication therapy can offer a little relief of the symptoms of functional dyspepsia (Evidence Grade 3), but most patients with functional dyspepsia are not infected with the bacteria and do not benefit (Evidence Grade 2).

### Treating Helicobacter pylori in Peptic Ulcer Disease

- *H. pylori* eradication therapy considerably reduces the risk for reoccurrence of a peptic ulcer (Evidence Grade 1).

- *H. pylori* eradication therapy is more effective than acid inhibitors alone in preventing reoccurrence of a bleeding peptic ulcer (Evidence Grade 1). The conclusion applies only to patients without concurrent non-steroidal anti-inflammatory drug (NSAID) therapy.

- One week of triple therapy for *H. pylori* eradication that is not followed by acid inhibition therapy is as effective as one week of triple therapy for *H. pylori* eradication followed by 2–3 week acid inhibition therapy when it comes to both healing duodenal ulcers (Evidence Grade 3) and relieving their symptoms (Evidence Grade 3).

### Gastro-oesophageal Reflux Disease

- Normal doses of PPIs are more effective than H2RAs for treating gastro-oesophageal reflux disease (GERD) with coexisting oesophagitis (Evidence Grade 1). Longer treatment periods and higher doses of PPIs lead to healing of oesophagitis in more patients (Evidence Grade 1).

- Continuous PPI therapy is more effective than on-demand PPI therapy for long-term treatment of GERD with coexisting oesophagitis (Evidence Grade 1). On-demand PPI therapy and continuous PPI therapy are equally effective for long-term treatment of GERD without oesophagitis (Evidence Grade 1).

- Long-term PPI therapy is safe (Evidence Grade 1) and equally effective as surgery (Evidence Grade 2), making it suitable for younger people as well. Occasional deaths and frequent adverse effects have been reported in connection with surgical intervention (Evidence Grade 1).

**Barrett's Oesophagus**

- Barrett's oesophagus increases the risk of developing oesophageal adenocarcinoma (Evidence Grade 3), but the extent to which the risk increases is not fully known.

- No studies have proven the benefits of systematic endoscopic examinations (screening) to identify people with Barrett's oesophagus or regular endoscopic examinations of people with Barrett's oesophagus (surveillance).

- There is a lack of well-designed scientific studies showing that acid inhibitor therapy or anti-reflux surgery significantly reduce the risk of developing oesophageal adenocarcinoma in patients with Barrett's oesophagus.

**Fact Box 1** Study Quality and Relevance, Evidence Grade.

***Study quality and relevance*** refers to the scientific quality of a particular study and its ability to reliably address a specific question.

***Evidence Grade*** refers to the total scientific evidence for a conclusion, ie, how many high-quality studies support the conclusion.

**Evidence Grade 1 – Strong Scientific Evidence**
A conclusion assigned Evidence Grade 1 is supported by a good systematic literature overview with a meta-analysis or at least two studies with high quality and relevance among the total scientific evidence. If some studies are at variance with the conclusion, the Evidence Grade may be lower.

**Evidence Grade 2 – Moderately Strong Scientific Evidence**
A conclusion assigned Evidence Grade 2 is supported by a systematic literature overview with a meta-analysis that fails to meet the requirements for a good systematic overview in some respect or at least one study with high quality and relevance and two studies with medium quality and relevance among the total scientific evidence. If some studies are at variance with the conclusion, the Evidence Grade may be lower.

**Evidence Grade 3 – Limited Scientific Evidence**
A conclusion assigned Evidence Grade 3 is supported by a systematic literature overview with a meta-analysis that fails to meet the requirements for a good systematic overview in several respects or at least two studies with medium quality and relevance among the total scientific evidence. If some studies are at variance with the conclusion, the scientific evidence may be lower.

**Insufficient Scientific Evidence**
If no studies meet the quality and relevance criteria, the scientific evidence is rated as insufficient to draw any conclusions.

**Contradictory Scientific Evidence**
If different studies are characterised by equal quality and relevance but generate conflicting results, the scientific evidence is rated as contradictory and no conclusions can be drawn.

## Additional Research Needs

Both the underlying causes and progress of functional dyspepsia are still unknown. That is largely true of GERD as well. Although researchers have identified the decisive role played by *H. pylori*, there are large gaps in our knowledge about the causes and progress of peptic ulcer disease, as well as the factors that determine whether or not life-threatening complications develop.

Knowledge is largely lacking about the significance of gender in these conditions. The relevance of lifestyle factors – such as diet, physical activity and body weight – for the development of GERD and the prospects for influencing its progress also requires additional research. Clinical trials concerning the role of healing of oesophagitis, as well as the long-term effects of both medical and surgical intervention for reflux disorders, would also be beneficial.

More studies are needed that examine the impact of *H. pylori* eradication therapy on a broader scale in the context of everyday health care.

More reliable information is required about how much of a risk factor Barrett's oesophagus is for oesophageal adenocarcinoma, as well as the effectiveness of endoscopic screening and surveillance. Additional efforts are needed to identify clinically useful indicators or markers for cancer risk.

Both general and targeted health economic studies covering the entire field of dyspepsia and reflux disorders are badly needed.

Independent, community-financed research is particularly urgent.

# SBU's summary

## Introduction

Dyspepsia, which has multiple causes, is either organic or functional. Organic dyspepsia refers to conditions caused by diseases of the upper gastrointestinal tract – particularly peptic ulcers, as well as oesophageal and gastric cancer – that can be detected during an examination.

Functional dyspepsia is the default diagnosis when a thorough clinical investigation does not point to an organic cause or demonstrably impaired gastrointestinal function.

Gastro-oesophageal reflux disease (GERD) involves the backflow of stomach contents through the lower oesophageal sphincter into the oesophagus, typically causing the symptoms of heartburn and acid regurgitation or waterbrash (bitter regurgitation). Oesophagitis can sometimes be detected by an OGD. Patients with typical symptoms of GERD who exhibit no signs of oesophagitis during an OGD are diagnosed as having endoscopy-negative reflux disease (ENRD).

The majority of patients with peptic ulcer disease have inflammatory changes in the lower (distal) stomach caused by *H. pylori*. Half of the world's population is infected with the bacteria. Most people contract it before the age of one and have it all their lives if left untreated. The bacteria cause a number of different conditions, including peptic ulcers and even gastric cancer. But the infection produces no symptoms in most people.

## Investigating Dyspepsia in Current Clinical Practice

*Case History*

Based solely on a patient's particular symptoms, it is generally impossible to determine the cause of dyspepsia with any reasonable certainty. But the patient's narrative of how the disorder developed can render various diagnoses more or less probable, while facilitating the choice of examinations that will confirm or rule them out. For example, heartburn and acid regurgitation point to GERD. The persistence and progress of symptoms are also integral to investigating dyspepsia.

Clarification is needed concerning the symptoms or constellation of symptoms that call for a particular diagnostic or therapeutic approach. In accordance with current clinical practice, certain alarm symptoms – including weight loss, melena (black stool), hematemesis (vomiting blood), and dysphagia (difficulty swallowing) – that may accompany dyspepsia call for prioritised examinations. Another such alarm symptom is the development of new dyspeptic symptoms in patients over 50 years of age.

*Oesophago-gastro-duodenoscopy and other Examinations*

Oesophago-gastro-duodenoscopy (OGD) is a particularly effective examination for identifying possible organic causes of dyspepsia. Between 10% and 20% of patients with more than temporary dyspepsia have peptic ulcers. Approximately 10% have reflux oesophagitis, and fewer than 1% have cancer. An endoscopy can permit all three diagnoses with a high degree of certainty.

24-hour pH monitoring of the oesophagus provides valuable information when investigating dyspepsia, but the results must also be considered in light of the patient's case history and an endoscopy. Such monitoring is associated with certain difficulties in terms of interpreting the results, ie, determining what is normal and what is pathological.

Ultrasonography is useful for diagnosing the pathological processes in the bile ducts, liver and pancreas that occur in approximately 5% of dyspepsia patients.

*Helicobacter pylori – Diagnosis*

The routine methods in primary care are to investigate the presence of antibodies against *H. pylori* in the blood (the rapid test, yielding immediate results) or serum samples that are sent to the laboratory. Surface markers for the presence of *H. pylori* can also be detected in a stool sample. The urea breath test, based on the ability of *H. pylori* to break down the swallowed urea, is considered to be the most reliable. *H. pylori* infection can also be demonstrated by microscopically examining tissue samples taken from the stomach mucosa during an endoscopy. Samples for cultivating *H. pylori* can also be taken during this procedure.

## Project Methodology

### Literature Review

A systematic review of scientific studies was central to summarising the current state of knowledge about the treatment of dyspepsia and related disorders. The review focused primarily on randomised controlled trials (RCTs) and systematic literature overviews, based chiefly on RCTs.

Proceeding from specific terms, the Medline database was searched for studies in English language publications only. Because this report is partly a follow-up on the previous SBU report Dyspepsia – Methods of Diagnosis and Treatment (2000), the search for certain areas was limited to January 1999 to 2005. The search for other areas went back to 1996. Each chapter of the main report provides more details about the associated literature search.

A questionnaire about the treatment of uninvestigated dyspepsia in clinical practice was sent to general medical practitioners. A questionnaire study was also conducted at all of Sweden's endoscopy units. The scope of surgery for GERD, as well as pharmaceutical sales in the various therapy areas, is also covered.

## Results of the Literature Review

### Uninvestigated Dyspepsia and Uninvestigated Gastro-oesophageal Reflux

There are two traditional approaches to treating patients with uninvestigated dyspepsia. Empirical therapy often includes acid inhibitors, dietary counselling and reassurance – or treatment can be based on the results of an OGD (prompt endoscopy).

Existing studies that include patients who have uninvestigated dyspepsia have not found any difference in symptom relief between empirical therapy with acid inhibition and treatment following an OGD (Evidence Grade 3).

An additional approach has been adopted in recent years by which an *H. pylori* test is first performed, followed by the choice of an investigation and treatment strategy. One strategy (test-and-treat) is to immediately eradicate any *H. pylori* that is detected without performing an OGD. The other strategy is to perform an OGD if *H. pylori* is detected and treat only patients with demonstrable peptic ulcer disease. In other words, *H. pylori* infection is not treated if there are no current or previous signs of a peptic ulcer.

Systematic literature overviews show that the test-and-treat strategy appears to be more cost-effective than prompt endoscopy. Problems with translating relative prices from studies in other countries, as well as evaluating the impact of differing ways of structuring the healthcare sector, make it difficult to assess their relevance to cost-effectiveness issues in Sweden.

Oesophageal acid exposure correlates well with isolated gastro-oesophageal reflux symptoms, at least in younger patients. The patient group is increasingly given empirical therapy with acid inhibitors.

One conclusion from the literature review is that both PPIs and H2RAs relieve the symptoms of GERD (Evidence Grade 1). PPIs are more effective than H2RAs in relieving or wholly eliminating symptoms (Evidence Grade 1). A considerable percentage of patients who are treated empirically for uninvestigated gastro-oesophageal reflux symptoms are satisfied with on-demand PPI therapy or continuous H2RA therapy (Evidence Grade 3).

*H. pylori* is a documented risk factor for gastric cancer, causing an estimated 60–90% of all cases. The problem is that the people with *H. pylori* who will later develop peptic ulcer disease or gastric cancer cannot be readily identified by means of currently available techniques. The incidence of gastric cancer is declining in Sweden, and it is very uncommon among people under 50 years of age.

The literature review shows that both advanced age and the presence of alarm symptoms in people with dyspepsia increase the probability of an underlying malignant tumour (Evidence Grade 3). But a considerable percentage of patients with a tumour have no alarm symptoms at their first medical consultation (Evidence Grade 3).

### Functional Dyspepsia

Functional dyspepsia refers to pain, ache or discomfort in the upper gastrointestinal tract unexplainable by observable organic changes. The symptoms usually follow eating. In addition to pain, patients with functional dyspepsia often have nausea, early satiety, abdominal bloating and distension of the upper gastrointestinal tract.

The term functional dyspepsia previously included the symptoms of heartburn and gastro-oesophageal reflux as well. The Rome I criteria for functional gastrointestinal disorders excluded those symptoms from the term and associated them with GERD instead. The underlying causes of functional dyspepsia remain unknown. SBU's 2000 report found that drug therapy has highly limited benefits for the disorder.

Following are some of the questions addressed by the current report concerning drug therapy for functional dyspepsia.

*Do acid inhibitors relieve symptoms more effectively than placebo?*
According to meta-analyses, drugs that inhibit the production of gastric acid provide some relief of functional dyspepsia symptoms (Evidence Grade 3). But because the constellation of symptoms bears certain similarities to that associated with non-oesophagitis reflux disease, analysing the impact of acid inhibitors on functional dyspepsia is difficult.

*Does drug therapy relieve symptoms more effectively than placebo when there is coexisting H. pylori infection?*
*H. pylori* eradication therapy provides a little relief of functional dyspepsia symptoms (Evidence Grade 3). However, most patients with functional dyspepsia either are not infected with *H. pylori* or obtain no relief from the therapy (Evidence Grade 2).

*Are PPIs more cost-effective than placebo?*
Because the meta-analysis reviewed was inconclusive, the question of the relative cost-effectiveness of PPIs and placebo in relieving functional dyspepsia symptoms cannot be answered.

**Helicobacter pylori and Treatment of Peptic Ulcer Disease**

*H. pylori* infection is ordinarily contracted during infancy. Absent treatment, the infection lasts a lifetime and is somewhat more common in adult males than females, though equally prevalent in girls and boys. Approximately 30% of Swedish patients age 30–50 have *H. pylori*. The bacteria are estimated to cause 95% of duodenal ulcers, 70% of gastric ulcers and at least 70% of gastric cancers. An estimated 10–20% of people with *H. pylori* develop a peptic ulcer at some point in their lives. One of the main problems is that it is not currently possible to predict which people

with the bacteria will remain symptom-free and which will develop peptic ulcer disease or cancer. As opposed to gastric cancer, peptic ulcers remain a common condition.

There are two main kinds of peptic ulcers – gastric and duodenal. Studies indicate that 4–6% of Scandinavians have peptic ulcers. Although both gastric and duodenal ulcers were once more common among Scandinavian men than women, the current trend is for the gap to narrow. The risk of complications, such as a bleeding or perforated peptic ulcer, is considerable. Current data indicate that 40–50 Swedes per 100 000 have bleeding peptic ulcers every year and that approximately 6% of them die. In other words, peptic ulcer disease not only causes great human suffering, but generates substantial costs for the community.

The current literature review led to the following conclusions. *H. pylori* eradication therapy considerably reduces the risk that a gastric ulcer will reoccur (Evidence Grade 1). But the scientific evidence is insufficient to draw any conclusions concerning the risk of reoccurrence after 1–2 week eradication therapy compared to continuous maintenance therapy with acid inhibitors in the absence of preceding eradication.

*H. pylori* eradication therapy considerably reduces the risk that a duodenal ulcer will reoccur (Evidence Grade 1). One week of triple therapy for *H. pylori* eradication that is not followed by acid inhibition therapy is as effective as one week of triple therapy for *H. pylori* eradication followed by 2–3 week acid inhibition therapy when it comes to both healing duodenal ulcers (Evidence Grade 3) and relieving their symptoms (Evidence Grade 3).

*H. pylori* eradication therapy for 1–2 weeks that is not followed by continuous maintenance therapy with acid inhibitors has not been shown to pose a different risk for reoccurrence of a duodenal ulcer than regular maintenance therapy with acid inhibitors in the absence of preceding *H. pylori* eradication therapy (Evidence Grade 1).

Whether or not it is followed by continuous maintenance therapy with acid inhibitors, *H. pylori* eradication therapy is more effective than acid inhibitors alone in preventing reoccurrence of

a bleeding peptic ulcer (Evidence Grade 1). Because the analysis included patients who received little or no concurrent NSAID therapy, the conclusion does not extend to those receiving such therapy.

None of the studies that served as the basis for evidence grading in accordance with the above focused on analysing possible gender differences.

### Gastro-oesophageal Reflux Disease

Gastro-oesophageal reflux refers to the backward flow of stomach contents through the lower oesophageal sphincter into the oesophagus, normally after eating and during physical activity. Such episodes are short-lived, and the musculature of the oesophagus usually returns the refluxate to the stomach very quickly. Protection factors in the saliva and oesophageal mucosa, as well as the saliva's buffering capacity, counteract the harmful effects of the refluxate. Gas reflux (belching), primarily of swallowed air, stems from a protective reflex.

Increased gastro-oesophageal reflux or failure of the protective factors can give rise to symptoms or oesophageal injury. The line between a healthy and pathological state is ill-defined. It is well-documented that symptoms traceable to gastro-oesophageal reflux are common among the general population and of a nature such that many people never seek medical advice. But some patients with demonstrable reflux have no (or only negligible) symptoms, and the disorder is not detected unless an oesophageal stricture or cancer develops.

Due to the ill-defined line between a healthy and pathological state, an unequivocal definition of what constitutes a reflux disorder is not currently possible.

According to the literature review, a normal PPI dose for eight weeks is more effective than H2RAs or other strategies in treating a reflux disorder with coexisting oesophagitis (Evidence Grade 1). Longer treatment periods and higher doses of PPIs lead to healing of oesophagitis in more patients (Evidence Grade 1). But no

published articles address the question of whether healing of oesophagitis should be monitored.

Continuous PPI therapy is more effective than on-demand PPI therapy for long-term treatment of a reflux disorder with coexisting oesophagitis (Evidence Grade 1). But there is no scientific evidence that PPIs are more effective than H2RAs for initial treatment of endoscopy-negative reflux disease (ENRD). On-demand PPI therapy is more effective than placebo and equally effective as continuous PPI therapy for long-term treatment of ENRD (Evidence Grade 1).

GERD is a chronic disorder to which younger people are also susceptible. Given that treatment continues for decades, special consideration must be given to efficacy, safety and alternatives to drug therapy. Long-term PPI therapy is also safe for younger people (Evidence Grade 1) and equally effective as surgery (Evidence Grade 2). Surgical intervention leads to occasional deaths and a high percentage of adverse effects (Evidence Grade 1).

### Barrett's Oesophagus

Barrett's oesophagus is a condition in which the normal oesophageal mucosa undergoes a change (intestinal metaplasia) due to chronic acid regurgitation. The diagnosis cannot be made on the basis of an endoscopic examination alone, but requires an analysis of tissue samples. The growing clinical interest in Barrett's oesophagus during the past few decades is due to its correlation with gastro-oesophageal reflux, as well as the greater incidence of oesophageal adenocarcinoma.

People with Barrett's oesophagus have poorer protection against gastro-oesophageal reflux, as well as more oesophageal exposure to gastric juice, than others with GERD. The extent of Barrett's mucosa is also related to the severity of the GERD. While the incidence of Barrett's oesophagus among the general population is not fully known, it is reported to occur in 1–29% of people who undergo an oesophageal endoscopy due to gastro-oesophageal reflux symptoms.

The literature review concluded that Barrett's oesophagus increases the risk of developing oesophageal adenocarcinoma (Evidence Grade 3), but the extent to which the risk increases is not fully known. Clinically useful risk factors for oesophageal adenocarcinoma in people with Barrett's oesophagus are visual abnormalities in Barrett's mucosa during an endoscopy.

No randomised trials have examined the benefits of endoscopic screening of people with gastro-oesophageal reflux symptoms in order to identify those who have Barrett's oesophagus. Studies are also lacking when it comes to the impact of endoscopic surveillance of patients with Barrett's oesophagus to detect early-stage cancer. As a result, the scientific evidence for both treatment strategies is insufficient. Evidence is also lacking that acid inhibitors or anti-reflux surgery significantly reduces the risk of developing oesophageal adenocarcinoma in patients with Barrett's oesophagus.

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Below is a brief summary of the mission assigned to SBU by the Swedish Government:

- SBU shall assess healthcare methods by systematically and critically reviewing the underlying scientific evidence.
- SBU shall assess new methods as well as those that are already part of established clinical practice.
- SBU's assessments shall include medical, ethical, social and economic aspects, as well as a description of the potential impact of disseminating the assessed health technologies in clinical practice.
- SBU shall compile, present and disseminate its assessment results such that all parties concerned have the opportunity to take part of them.
- SBU shall conduct informational and educational efforts to promote the application of its assessments to the rational use of available resources in clinical practice, including dental care.
- SBU shall contribute to the development of international co-operation in the field of health technology assessment and serve as a national knowledge centre for the assessment of health technologies.

## Dyspepsia and Gastro-oesophageal Reflux

The SBU report is based on a systematic and critical review of the scientific literature. It is one of a series of scientific reports published by SBU (The Swedish Council on Technology Assessment of Health Care).

The Summary and Conclusions of the report, presented in this booklet, have been approved by the SBU Board of Directors and the Scientific Advisory Committee.

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