What you should know about gallstone treatment
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## Contents

- **Foreword** .................................................. 4
- **Location and function of the gallbladder** ........... 6
- **How do gallstones develop?** .......................... 10
- **Gallstones are not all alike: differences in composition** .................................................. 13
- **Modern treatment options for gallstone disease** 15
  - Drug therapy (oral dissolution) ......................... 16
  - Shock wave lithotripsy (ESWL) ........................ 22
  - Surgery ...................................................... 26
  - Removal of stones from the bile ducts .................. 28
- **Gallstone recurrence: Can it be prevented?** ........ 29
- **Nutrition tips to prevent stone recurrence** ........... 31
- **A final word** .................................................. 32
Foreword

Dear patient,

Gallstones are much more common than you might think. In Western industrial nations, about one in five adults will develop stones in the gallbladder or bile ducts at some point in their lives.

In many cases, however, persons with gallstones will be unaware of this fact, since only about 20% of them will experience typical symptoms. These “silent” gallstones have the potential to become “loud” and, if they do, symptoms such as cramping abdominal pain, colics and disturbances in the function of the gallbladder, liver or pancreas demand exact diagnosis and, in some cases, prompt therapy.
Gallstones: how they form and what can you do?

Surgical removal of the gallbladder together with the stones?

Attempt to “pulverize” the gallstones using shock waves, dissolve them using drugs or a combination of methods?

Can the recurrence of gallstones be prevented?

This booklet will provide answers to these questions and will bring you up to date on the current options in gallstone therapy.

You will not only better understand the function of your gallbladder but will become familiar with the available therapeutic methods.

If, after reading this booklet, you still have questions, please consult your physician, who will assist you further.

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Location and function of the gallbladder

The gallbladder is found in the upper right corner of the abdomen beneath the liver. Its function is very easy to explain: It collects and concentrates the bile that is produced in the liver cells and carried by the bile ducts to the gallbladder. The gallbladder also controls the release of bile into the duodenum (small bowel), where it assists in the digestion of our food.
Schematic drawing of the gallbladder, stomach and liver.
Why is the reservoir function of the gallbladder important?

Our livers produce about 1 liter of bile each day. This bile is collected in the gallbladder, where it is concentrated and stored.

As omnivores (organisms whose diets include foods of both animal and vegetable origin), we require not only adequate chewing, gastric juice and intact bowel function to digest our food, but also special bile acids that assist with utilization of nutrients.
Since we eat different amounts of food at different times during the day, we require an adequate supply of both bile and other digestive juices for these different digestive events.

Certain nutrients, especially dietary lipids (including cholesterol), require the presence of bile for their adequate digestion. For this reason, following a meal, the gallbladder contracts and forces the bile through the bile duct into the duodenum. Here, it is mixed with the partially digested food leaving the stomach.

The result is a mixture of food and bile in which the individual nutrients are more completely dissolved and more easily digested than in the absence of bile. Bile acids are substances contained in the bile that act as emulsifiers promoting adequate mixing. The bile also contains cholesterol, pigments, proteins, lecithins, salts and water.
How do gallstones develop?

The answer to this question is also very simple: It all has to do with an imbalance in the composition of the bile, which can have many causes.

As we have seen above, bile is a complicated mixture whose many components remain in solution only if the balance between cholesterol, bile acids and so on is exactly maintained and the bile is continually mixed by regular contractions of the gallbladder.

Imbalance in the proportions of the individual components can have many causes:

– Disturbances in the production or transport of bile in the liver, where bile is formed
– Excessive dietary consumption of high-fat foods
– Disturbances in the ability of the gallbladder to concentrate the bile or inadequate mixing of the bile by the gallbladder
– Loss of bile acids due to other diseases
– Inborn (genetically determined) abnormalities

One possible result of these disturbances is the deposition of crystals (microscopic at first) in the gallbladder.

Once formed, these small cholesterol crystals may continue to grow in size over months and years. In most cases, you will not have the slightest idea that this is happening.

It is only when the gallbladder can no longer adequately contract, or when the opening of the gallbladder or the bile ducts are partially or completely blocked by stones that there is a back-up of bile. This is the point at which the painful symptoms begin.
Who has an increased risk of developing gallstones?

An unusually large number of persons with gallstones are observed to consume diets high in calories and especially high in fat.

An increased concentration of cholesterol in the bile may, however, also be seen during long periods of fasting. There is a tendency to gallstone formation when high cholesterol concentrations in the bile are not balanced by increased secretion of bile acids.

Bile acids may also be lost due to chronic diseases of the small bowel and colon (Crohn’s disease, ulcerative colitis) or following surgery.

The following groups of people are subject to an increased risk of developing gallstones:

– Overweight and obese persons
– Patients with certain metabolic diseases
– Patients with diabetes
– Patients with liver diseases (cirrhosis, hepatitis)
– Patients with diseases of the small bowel and colon

There is also an increased risk of gallstones during pregnancy.

This is probably due to changes in metabolic processes occurring during pregnancy, such as:

– Changes in hormonal patterns
– Reduced ability of the gallbladder to contract due to the increasing size of the fetus
These or similar hormonal issues are probably also responsible for the fact that women in general have a higher risk of developing gallstones than do men.

We have seen, which factors promote the formation of gallstones. In the next section, we will discuss the various types of gallstones and see how these help determine the best type of therapy for each individual patient.
Gallstones are not all alike: differences in composition

Depending on the exact nature of the disturbance in the production of the bile fluid, patients may develop stones of different composition. In many cases, the main component of the gallstone may be cholesterol. In other patients, however, there may be varying amounts of other substances, such as pigments, as well as salts (for example, calcium), components of mucous secretions (mucins) and proteins.

There are also many intermediate types, and these variations differ widely from patient to patient.

The following table and illustration provide an overview of the main types of gallstones.

<table>
<thead>
<tr>
<th>Type</th>
<th>Major contents</th>
<th>Prevalence</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cholesterol stone</td>
<td>Cholesterol</td>
<td>70–90%</td>
</tr>
<tr>
<td>Composite stone</td>
<td>Cholesterol, pigments</td>
<td>10–30%</td>
</tr>
<tr>
<td>Pigment stone</td>
<td>Pigments, calcium, mucins</td>
<td>5–10%</td>
</tr>
</tbody>
</table>
Differences in gallstone composition have therapeutic consequences, as we shall now discuss.

Different types of gallstones in humans.
Gallstone treatment

Modern treatment options for gallstone disease

Treatment options are directed at the composition of gallstones and the severity of the disease. In individual cases, the physical constitution of the patient may play a major role in deciding for or against a certain form of therapy.

As you will learn in the following sections, modern medicine offers a number of therapeutic options for patients with gallstone disease:

– Oral dissolution of gallstones using drugs
– Shock wave treatment
– Surgery
– Adjuvant dietary measures

First, we must emphasize that “silent” gallstones (i.e., those which have caused no symptoms) are generally observed, but not treated.

It is only when gallstones begin to cause complaints that they are treated. Stones in the bile ducts, however, are always treated, regardless of symptoms.
Drug therapy (oral dissolution)

The principle: reversing the process of gallstone formation

Bile acids, an important component of the bile, are produced by the liver to emulsify cholesterol, making it more soluble.

As we have seen above, in many cases gallstones consist predominantly of cholesterol crystals. The regular intake of certain litholytic bile acids in highly purified form can chemically dissolve these stones. Hence, in principle, the process of stone formation is reversed.

One bile acid, known as ursodeoxycholic acid (UDCA), has been especially useful for this treatment.

Which gallstones are especially suitable for medical treatment?

Patients whose stones consist predominantly of cholesterol respond especially well to treatment with UDCA. These stones, because they have little or no calcium, are not seen on X-rays but are reliably detected and located by ultrasound.
Cholesterol stone. It is light-colored and somewhat translucent.

Many floating stones (less than 5 mm in diameter) in the fluid-filled gallbladder (X-ray image).
Ideally suited for oral dissolution therapy are so-called “floating” stones. Their density corresponds to that of the bile and therefore do not settle to the bottom of the gallbladder.

The success of oral dissolution therapy with UDCA depends on a number of requirements being met:

– Maximum stone diameter should not exceed 5–10 millimeters
– Total stone mass should not exceed one-third of the volume of the gallbladder
– The gallbladder must be fully functional
– The bile ducts must be free of obstruction
– Patients should not be taking certain medications (clofibrate, antacids, cholestyramine)

What must you know about oral dissolution of gallstones?

First, patience is a virtue: Just as the development of gallstones takes months or even years, dissolution of gallstones with the help of bile acids does not occur overnight.

Duration of oral dissolution therapy

Depending on stone size, type and number, therapy may take between 3 months and 2 years. Maximum stone size is the main factor responsible for the duration of therapy.
Regular and consequent compliance with your medication is the fundamental requirement for successful stone dissolution. You will take most of your medication in the evening, since it is especially at night that your liver produces bile fluid of a type that promotes the formation of gallstones.

Severe abdominal pain, fever or chills, as well as dark urine may point to a stone trapped in the bile duct. If you experience these symptoms, you must immediately seek medical attention!
Advantages of oral dissolution therapy

Therapy with ursodeoxycholic acid (UDCA) is practically free of side effects and has been proven safe and effective in many international clinical studies.

Without doubt, this is the gentlest method of removing gallstones.

Compared to other forms of therapy, especially surgery, oral dissolution with UDCA offers patients a number of advantages:

- Preservation of the gallbladder and normal bile flow
- Avoidance of surgery together with its risks and consequences (anesthesia, complications, scars, dietary restrictions)
- No pain, no absence from work

Success rates and follow-up examinations during oral dissolution therapy

Patients who regularly take their prescribed medication can expect successful oral dissolution of gallstones in about 40–70% of cases.

Reduction in stone size is determined by ultrasound. Female patients should avoid becoming pregnant during therapy.
A final request:

Oral dissolution therapy for gallstones is only successful when you take your medication as prescribed. Please do not tamper with the dosage and never simply discontinue therapy without consulting your physician. In such cases, gallstones will continue to grow in size and may result in severe, acute symptoms that may even require surgery!
Treatment of gallstones with shock wave lithotripsy (ESWL)

Extracorporeal shock wave lithotripsy (ESWL) of gallstones was first used in 1985. The method had been initially introduced in 1980 for the treatment of kidney stones.

Objective of this method is to reduce the size of gallstones without resorting to surgical intervention. One very effective way of doing this is by the use of special shock waves originating from a generator located outside the body (“extracorporeal”).

The principle

Shock waves focused exactly on the gallstone shatter it to tiny fragments.

Schematic representation of shock wave therapy. The patient lies on a water cushion above the shock wave reflector. Shock waves are generated following precise placement of the stone in the shock wave focus.
The treatment

A treatment session takes about 30–60 minutes. During treatment, the patient lies atop a shock wave reflector, which focuses the shock waves exactly on the patient’s stone.

With the stone under constant monitoring by ultrasound, shock waves are generated and the disintegration of the stone is observed.

Depending on stone type, size and number, one or sometimes several treatments may be necessary before the stone is destroyed.

The resulting small stone fragments are dissolved much more rapidly than large, compact stones by the action of UDCA.

Also, some fragments are actually evacuated automatically by the gallbladder each time it contracts.

Which stones are suitable for shock wave treatment?

The technique is especially suitable for patients with solitary stones in the gallbladder and for stones trapped in the bile ducts that have not been amenable to treatment with other methods, such as endoscopic stone removal.

Despite advances in this technology, there are still some restrictions on the use of lithotripsy.
Pre-requisites for the lithotripsy of gallstones

Currently considered amenable to treatment with shock wave lithotripsy are patients with:

- Solitary, non-calcified stones up to 2 cm in diameter
- Normal blood coagulation
- No inflammation of the gallbladder or pancreas
- Female patients may not be pregnant

Advantages and success rate of shock wave treatment

As with oral dissolution therapy, the main advantages of lithotripsy are preservation of the gallbladder and avoidance of surgery or other invasion of body cavities.
The method has become relatively quick and can be performed without any significant risk. Especially in the recent past, it has been optimized with many technical refinements.

In suitable cases, lithotripsy can be performed on an outpatient basis without analgesic therapy.

Complete stone clearance and resolution of symptoms can be expected within a few months in about 60–90% of patients treated with shock wave lithotripsy.

The small stone fragments remaining after shock wave therapy are especially suitable for further dissolution by UDCA.
Surgical treatment of gallstones

There has also been progress in the surgical treatment of gallstones.

If surgery is recommended, patients should understand that:

– Surgical removal of the gallbladder is one of the most common and safest surgical procedures.
– For many patients brought to the hospital with highly acute symptoms, surgery is often the only sensible alternative and may be life-saving. It has therefore preserved its paramount position in the treatment of gallstones.

Although surgical removal of the gallbladder remains “routine” in modern surgery, the details of the procedure may be much more problematic for the individual patient.

In addition, about 25% of surgically treated patients continue to report similar complaints after surgery.

Because surgery, from the point of view of the patient, represents an “irrevocable” measure, careful consultation between the patient and his physician should explore whether any of the non-surgical alternatives offer acceptable prospects of success.

If these methods do not prove successful in improving the patient’s situation, surgery always remains as a final option.
Today, most gallstones are removed using endoscopic surgical techniques through several small incisions in the abdominal wall or near the navel. This usually avoids creating the unpleasant large scars associated with conventional open surgery and significantly reduced the period of hospitalization associated with the procedure.
Removal of stones from the bile ducts

Today, bile *duct* stones are usually treated with endoscopic methods. You may already be familiar with endoscopy from the method of examining the stomach or colon.

For treating bile *duct* stones, an endoscope is used to “capture” the stone in a basket, which, following widening of the opening of the bile duct into the bowel (papilotomy), opens, grasps the stone and is then removed with the stone.

Large and impacted stones, or those trapped in bile ducts within the liver itself can usually be safely and successfully reduced in size with shock waves.

In some centers, lasers (high-energy beams of light) have been successfully used to reduce the size of stones trapped in the bile ducts.

*X-ray image of the endoscope and stones within the bile duct.*
Gallstone recurrence: Can it be prevented?

One large problem remains: Even after successful treatment and complete disappearance of gallbladder stones, no way has yet been found to stop the process responsible for stone formation.

As discussed above, the cause of stone formation lies to a great extent in metabolic disturbances in the liver. The exact molecular and biochemical processes in the liver cells that are responsible for the production of bile fluid of a type that promotes stone formation are the subject of intense research but are far from being adequately understood.

Studies of stone recurrence in patients following successful stone clearance have shown that 30–50% of them will again develop gallbladder stones within 5 years. Of these, however, only a minority again developed pain.

The high recurrence rate may partially be explained by the possibility that very small stones are often “invisible” to diagnostic imaging and are thus overlooked. These patients were therefore erroneously declared stone-free and therapy terminated prematurely.
Continue drug therapy

This leads to the logical next conclusion: continue treatment with UDCA for a period of about 3–6 months after evidence of stone clearance at ultrasound.

It is currently being studied whether longer-term, reduced-dose treatment with drugs can reduce the risk of stone recurrence. Long-term findings remain unavailable at this time.

Patients with a strong tendency to stone recurrence are today usually advised to consider surgical removal of the gallbladder.
Nutrition tips to prevent stone recurrence

Certain dietary measures may reduce your risk of developing recurrent gallstones:

- Avoid becoming overweight: Overweight patients suffer especially often from stone recurrence.
- Reduce your dietary intake of cholesterol. By consuming a diet low in cholesterol, patients can do much to extend as long as possible their freedom from gallstones.
- Eat several small meals distributed throughout the whole day, including a light late meal. This helps the gallbladder to mix the bile and hinders the formation of stones.
- A high-fiber diet, rich in vegetables, facilitates the digestive process and also works against the formation of gallstones.

Therefore: Consult your physician and follow his advice on diet and lifestyle!
A final word

Helping patients and physicians defeat diseases of the liver, stomach, bowel and biliary tracts is the main mission of the Falk Foundation e.V.

The purpose of this booklet has been to help you understand modern therapy options for patients with gallstones and to promote confidence and cooperation between physicians, patients, medical researchers, pharmaceutical manufacturers and the general public.

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