Progress report
Non-surgical removal of common bile duct stones

In Western countries most stones in the common bile duct originate from the gall bladder; only rarely do they arise de novo on the basis of biliary stasis and infection. Common bile duct stones that have been overlooked during a cholecystectomy have a particular clinical significance and often precipitate the need for a second operation.\(^5,34,37\) Despite routine intraoperative cholangiography, common bile duct stones are overlooked in 1 to 14\% of cases\(^23,39,41,60,74\). Because of the high rate of complications—over 50\%—that can be expected in cases of untreated cholelithiasis, the need to remove the stones from the bile duct is imperative. The majority of the procedures described aim either at destroying the stones in situ\(^2,3,7,10,15,17,19,23,27,33,34,35,38,43,47,49,56,58,62-64,66-70,73,78-80\) or removing them from the common bile duct by mechanical means\(^5,8,13-14,17,30,48,60-65,85\); their application thus requires the presence of an indwelling T-tube. Only recently have procedures been developed which open up a transhepatic\(^71,86\) or duodenal\(^20-22,26,28,45,46,61,72,88\) route of access to the common bile duct, and thus represent a true alternative to the surgical intervention that was formerly necessary.

Removal of common duct stones via a T-tube

Common bile duct stones that have been overlooked during surgery may later be disclosed after operation by cholangiographic follow-up examinations via the T-tube. In these cases, the T-tube permits probes and snares to be introduced so that stones can be mechanically removed from the bile duct under radiological or endoscopic control; it also allows the stones to be irrigated with a solvent for cholesterol or with substances that permit them to be fragmented.

Mechanical removal of stones

At the beginning of the '50s, attempts were made to remove stones from the common bile duct by increasing pressure and bile flow in the common bile duct while the sphincter of Oddi was simultaneously relaxed by drugs; several different methods were used: clamping the T-tube; promoting choleresis with decholin, olive oil, or magnesium sulphate; increasing the pressure in the common bile duct by using the evaporation pressure of ether; irrigation with physiological saline solution; and attempted relaxation of the sphincter by the administration of atropine, amyl nitrite, novocaine, or nitroglycerine\(^3,10,17,18,43,48,57,73,78,80\); (detailed references in \(^73\)).

The development in recent years of powerful x-ray units with television image intensifier systems and new catheter materials prompted surgeons and radiologists to try to remove common bile duct stones by means of a variety
of manipulations through an indwelling T-tube drain. In the majority of cases, following the Seldinger technique, catheters such as simple rubber catheter, bladder catheters, angiographic catheters, Fogarty catheters, or Dormia baskets were advanced into the common bile duct and attempts made to extract the stones, or to push them through the papilla into the duodenum\(^5,9,16,25\).

The efficiency of the manipulations described is difficult to assess, as the majority of publications were descriptions of successful extractions of individual stones. Only Mazariello has had experience with a larger number of cases. Since 1964 he has removed gallstones from the common bile duct by means of the inflexible Randell, Leger, or Mondet forceps, which he introduces through the channel of the connective tissue fistula that develops around the T-tube (sinus tract); in 204 of 220 patients (92.7%) the stone was successfully extracted. The introduction of the controllable catheter by Burhenne\(^3,13,16\) represented a considerable improvement on this method. The catheter is 25 cm long and its end can be deflected to \(90^\circ\) by remote control from outside (Medi Tech, Watertown, Mass 02172), by means of which it is easier to overcome the angle between the sinus tract and the distal and proximal side of the ductus hepatocholedochus. The procedure is thus shortened and simplified and patient and therapist are exposed to less radiation. According to Burhenne's experience—he succeeded in extracting stones from the common bile duct in 95 of 100 patients—the following procedure has proved its value.

As a prophylactic measure the surgeon should use a particularly wide-lumened T-tube (no 14-16 French), which is led out subcostally at the right side in the midclavicular line to make the shortest possible direct connection to the common bile duct. If radiological examination after the operation demonstrates the persistence of common bile duct stones, the T-tube should be left in place for one to two months so that an adequate connective tissue fistula can develop. The stone extraction can be made without premedication or anaesthesia and without admitting the patient to hospital. After extraction of the T-tube the special controllable polyethylene catheter (25 cm long outside diameter 4.3 mm or No. 13 French; inside diameter 2.7 mm or No. 8 French) is introduced into the common bile duct at the level of the bile duct stone. The manipulation is carried out under intermittent injection of contrast medium through the catheter and under continuous radiological control. Subsequently, a Dormia basket is introduced through the Burhenne catheter and is opened distal to the stone; after fixation of the stone in the Dormia basket the Burhenne catheter, including the Dormia basket and the fixed stone, are extracted through the channel of the fistula. Bile duct stones with a diameter of more than 1 cm easily fragment under the drawing of the Dormia basket; a bile duct stone with a diameter of 2 cm was fragmented electrohydrolitically by means of stone-crushing forceps\(^15\). Burhenne found few complications: in two of 100 patients a septicaemia developed which was well controlled by antibiotics. In one patient a short via falsa was made during the passage of the sinus tract, without extravasation and without any further complications.

The extraction of stones \textit{via} a T-tube under direct visual control was made possible by the use of small-calibre fibrescopes\(^76,87\). Yamakawa \textit{et al.}\(^87\) used for this purpose an improved choledochofibrescope with a flexible distal end,
the tip of which, having a diameter of 6.6 mm, can be deflected to 60° in two directions; a large channel of 2.6 mm allows the use of balloon-tipped catheters, basket forceps, or other stone forceps.

**CHOLEDODCHOLITHOLYSIS**

Ninety-five per cent of all gallstones found in Western countries are composed mainly of cholesterol, a normal constituent of the bile. Cholesterol, a fatty substance, is not soluble in water and is kept in solution in the bile by the formation of micelles with bile salts and lecithin. If the capacity of the bile to keep cholesterol in solution is exceeded, the cholesterol is precipitated and consecutive, potentially reversible, gallstone formation occurs (review of references in 7). Attempts to effect choledocholitholysis by the use of organic solvents can, in the majority of cases, be traced back to the first half of the century, ether3,10,17,59,66–68,72,78,80 and chloroform65,75,79 being the chief solvents used. *In vitro* studies carried out by Best et al.10 showed that, of 103 substances tested, only ether and chloroform were capable of dissolving the gallstone to any adequate degree. Intraductal instillation of ether and other organic solvents was carried out in more than 200 patients73; the greatest success rate is claimed by Pribram67 who was able to get rid of the common duct stones in all 51 patients treated. Because of the potential risks of the substances mentioned, however, these procedures are hardly ever used today69. For the dissolution of calcium-containing concretions, solution G, which is also used for dissolving kidney stones, has been used in individual cases58.

Since, physiologically, cholesterol is kept in solution in the bile by means of micelles formation with bile acids and phospholipids, attempts have been made to dissolve bile duct stones with bile acids. The disappearance of bile duct stones after long-term oral administration of bile acids (3-4 g per day) has been described by Rewbridge70 and Cole and Harridge24; this effect may possibly be due to an increased bile flow or an increase in the capacity of the bile to dissolve cholesterol. This therapeutic principle has recently again been examined by Way et al.82 and Lansford et al.49; sodium cholate (100 mM; pH 7.5) dissolved in physiological saline and sterilised by millipore filtration, was infused continuously over a maximum of 10 days at a flow rate of 30 ml per hour; a pressure valve in the infusion system prevented increases in pressure beyond 30 cm of water49. This treatment was successful in six out of eight and five out of six patients respectively49,82. As, in *in vitro* experiments19, human cholesterol stones in an appropriate sodium cholate solution lose only 10% of their initial weight in seven days, it can be assumed that the stones in the bile duct were not completely dissolved, but merely made small enough to pass through the papilla of Vater. The treatment frequently caused diarrhoea, which was manageable by the oral administration of cholesteramine. In addition to the cases of diarrhoea49,58,82, a temporary impaction of the stone with subsequent cholangitis and pancreatitis has been described49,82. Although comparative *in vitro* examinations have shown that the effectiveness in dissolving cholesterol stones decreases in the sequence oxycholic acid chenodeoxycholic acid, taurodeoxycholic acid, glycodeoxycholic acid, and cholic acid, for reasons of cost and because it is better tolerated, only the less effective cholic acid has been employed for infusion treatment of common bile duct stones7. According to *in vitro* studies19, the stone-dissolving effect of
the bile acids can be intensified by combining them with lecithin; to date, no corresponding clinical application has been effected.

**Fragmenting Substances**

The elimination of common bile duct stones by means of intraductal irrigation via a T-tube using solutions containing heparin is based on the following theory: bile salts keep cholesterol in solution by formation of micelles, which give the bile the properties of colloidal suspensions. The stability of such suspensions is related to the relative strength of the zeta potential of the suspended particles and the Van der Waals forces in the solution. An increase in the Zeta potential and thus an enhancement of the suspension stability of the bile can be achieved by the addition of highly negatively charged polar groups such as heparin. If the polar groups on the surface of the gallstone are positively charged and directed towards the solution, the presence of a large supply of negatively charged ions might lead to a dispersion and thus to a softening and fragmentation of the stone. In practice, patients with bile duct stones are treated with a continuous irrigation drip of heparinised saline through the T-tube at a dose of 25 000 units heparin per 250 ml saline every six hours for seven days; Gardner reported that bile duct stones were eliminated in 22 of 30 patients. Similar positive results have, in the meantime, been reported by other centres. The advantages of this treatment with heparin are that the substance is easily available, the absence of side-effects of the bile acids, and the potential dissolving effect in the case of non-cholesterol stones, too. As treatment with bile acids and with heparin is based on differing mechanisms, combination therapy might intensify the dissolving effect of the two components. And, indeed, in vitro studies have shown that the combination of sodium cholate and heparin produces the most marked stone-dissolving effect.

**Mechanical transhepatic removal of gallstones from the common bile duct**

Recently, attempts have been made to prograde cannulation of the common bile duct for stone extraction, the bile duct being approached from the intrahepatic bile ducts. It is reached either via a percutaneous liver puncture or by puncture via a hepatic vein by means of a catheter which is advanced through the jugular vein. It appears questionable whether this highly invasive procedure will acquire clinical importance.

**Removal of common bile duct stones via an endoscopic papillotomy of the papilla of Vater**

The design of fully-flexible duodenoscopes and the development of the technique of retrograde cannulation of the common bile duct via the papilla of Vater represent the basis for the removal of common bile duct stones with the aid of endoscopic papillotomy. The technique was developed in Germany by Demling et al. and in Japan by Kawai et al. and, at the present time, is finding increasing application in Western Europe, Japan, and the United States.
TECHNIQUE OF ENDOSCOPIC PAPILLOTOMY

Instruments

The same instruments are used as for diagnostic ERCP: duodenoscope JFB 2, prototype GFB 2 (Olympus Optical Company, Tokyo); prototype of the firm of Machida.

Instruments with prograde optical systems, such as the Olympus GIF D3 instrument, are employed in patients who have been subjected to a Billroth II gastrectomy. For papillotomy itself, the papillotomes developed by Soma\textsuperscript{45} and Classen and Demling\textsuperscript{20} are available; the great majority of interventions carried out to date have been performed with the papillotome developed by Classen and Demling. This papillotome comprises a plastic catheter containing a wire snare. The wire passes out of the lumen of the catheter 3 cm short of the tip and is reintroduced through the wall and into the lumen 5 mm from the tip. The wire is drawn taut by the application of tension to the proximal end of the catheter. By passing a high-frequency diathermy current along the wire, it can be used as an electric knife. The removal of the stones from the common bile duct is effected with Dormia catheters (Storz, Tuttingen; Olympus Optical Company, Tokyo) or with modified Fogarty catheters\textsuperscript{28}, which can all be passed down the instrument channel of the duodenoscope into the bile duct.

Technique

The intervention is effected after premedication as usually given for endoscopic interventions. After the introduction of the fibroscope, the anatomical situation of the duodenum, the papilla of Vater, and the bile and pancreatic ducts is examined both endoscopically and radiologically. Then, after cannulation of the papilla of Vater, the papillotome designed by Demling and Classen (‘pull technique’) is selectively introduced into the common bile duct under radiological and endoscopic control. After applying tension to the wire, and intermittently passing a mixed cutting and coagulation current, the ‘roof’ of the papilla is slit in the desired direction and for the desired length. The sudden emptying of contrast medium tinged with bile and mixed with mucus and small stones, and the endoscopic view into the lumen of the bile duct indicate that the newly created opening is adequately large. The entire operation takes 30 to 60 minutes. One week after the endoscopic sphincterotony, the duodenum, papilla of Vater, and the duct systems are examined with diagnostic ERCP. If stones still persist in the bile duct, the inadequately large sphincterotony is extended. If the extension of the incision seems either to hold no promise of success or to be dangerous, persistent stones can be removed with extraction instruments under radiological control.

RESULTS OF ENDOSCOPIC PAPILLOTOMY FOR REMOVAL OF COMMON BILE DUCT STONES

As yet more than 1100 endoscopic papillotomies (EPT) have been performed, mainly in Western Europe, for the removal of stones in the common bile duct (Table 1). In 63\% of patients the stones spontaneously disappeared some days after EPT. In a further 26\% of patients, stones could be extracted by means of the Dormia basket. Thus, in 89\% of cases EPT succeeded in removing common duct stones.
Table 1 Results of endoscopic papillotomy (EPT) for removal of common duct stones

<table>
<thead>
<tr>
<th>Centre</th>
<th>EPT</th>
<th>Spontaneous stone disappearance</th>
<th>Extraction</th>
<th>Remaining stones</th>
<th>Failed attempts</th>
</tr>
</thead>
<tbody>
<tr>
<td>M. Classen et al. (Hamburg)</td>
<td>141</td>
<td>97</td>
<td>17</td>
<td>20</td>
<td>2</td>
</tr>
<tr>
<td>M. Cremer (Brussels)</td>
<td>120</td>
<td>93</td>
<td>17</td>
<td>10</td>
<td>2</td>
</tr>
<tr>
<td>L. Demling et al. (Erlangen)</td>
<td>195</td>
<td>98</td>
<td>64</td>
<td>9</td>
<td>8</td>
</tr>
<tr>
<td>J. E. Geenen (Milwaukee)</td>
<td>30</td>
<td>21</td>
<td>5</td>
<td>5</td>
<td>2</td>
</tr>
<tr>
<td>K. Kawai (Kyoto)</td>
<td>37</td>
<td>20</td>
<td>5</td>
<td>6</td>
<td>4</td>
</tr>
<tr>
<td>C. Liguory (Paris)</td>
<td>104</td>
<td>84</td>
<td>22</td>
<td></td>
<td></td>
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<tr>
<td>L. Safrany (Münster)</td>
<td>344</td>
<td>196</td>
<td>125</td>
<td>28</td>
<td>21</td>
</tr>
<tr>
<td>P. R. Salmon (Bristol)</td>
<td>22</td>
<td>20</td>
<td>1</td>
<td></td>
<td></td>
</tr>
<tr>
<td>N. Soehendra (Hamburg)</td>
<td>68</td>
<td>43</td>
<td>11</td>
<td></td>
<td>14</td>
</tr>
<tr>
<td>D. S. Zimmon (New York)</td>
<td>46</td>
<td>25</td>
<td>19</td>
<td></td>
<td>2</td>
</tr>
<tr>
<td>Totals</td>
<td>1107</td>
<td>697 (= 63%)</td>
<td>284 (= 26%)</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Complications of Endoscopic Papillotomy

As with every invasive therapy, EPT is not without risk of serious complications (Table 2). In 94 (8.5%) of 1107 patients who underwent papillotomy for common duct stone removal, complications such as pancreatitis, perforation, bleeding, and septic cholangitis were observed. The EPT-related mortality in these patients was 1.08%. In our experience acute pancreatitis and retroperitoneal perforation are rare and relatively benign EPT complications. By contrast, septic cholangitis is a serious hazard, often necessitating urgent surgical intervention. Septic cholangitis results from stagnation of bile flow caused by common duct obstruction and simultaneous ascending infection facilitated by papillotomy. Thus the risk of septic cholangitis increases with the size and eventual impaction of the common duct stone. Besides cholangitis bleeding is a relatively frequent and most serious EPT complication. In our observations, bleeding resulted in nearly every case from a repeated, second or third large incision for the removal of big stones. Thus, the risk of bleeding seems to be correlated with the length of incision and with the size of the stone to be removed.

Present Limited Indications for Endoscopic Papillotomy

Experience obtained so far shows that endoscopic papillotomy is an effective and, compared with the surgical version, low-risk alternative to the surgical removal of stones from the common bile duct. The main disadvantage of this non-surgical technique is that it unavoidably damages the sphincter of Oddi. This disadvantage is, however, considerably diminished by the fact that, in patients with common bile duct stones, a secondary papillary stenosis is

Table 2 Complications of endoscopic papillotomy (EPT) for removal of common duct stones

<table>
<thead>
<tr>
<th>Centre</th>
<th>EPT</th>
<th>Bleeding</th>
<th>Perforation</th>
<th>Cholangitis</th>
<th>Pancreatitis</th>
<th>Mortality</th>
</tr>
</thead>
<tbody>
<tr>
<td>M. Classen et al. (Hamburg)</td>
<td>141</td>
<td>5 (3)</td>
<td>1 (?</td>
<td>9 (5)</td>
<td>1</td>
<td>2</td>
</tr>
<tr>
<td>M. Cremer (Brussels)</td>
<td>120</td>
<td>7 (3)</td>
<td>1 (1)</td>
<td>2</td>
<td>1</td>
<td>3</td>
</tr>
<tr>
<td>L. Demling et al. (Erlangen)</td>
<td>195</td>
<td>3 (2)</td>
<td>4 (2)</td>
<td>1</td>
<td>8</td>
<td>1</td>
</tr>
<tr>
<td>J. E. Geenen (Milwaukee)</td>
<td>30</td>
<td>1 (1)</td>
<td></td>
<td></td>
<td>1</td>
<td>0</td>
</tr>
<tr>
<td>K. Kawai (Kyoto)</td>
<td>37</td>
<td></td>
<td></td>
<td></td>
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<td>C. Liguory (Paris)</td>
<td>104</td>
<td>8</td>
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<td>1</td>
<td>1</td>
</tr>
<tr>
<td>P. R. Salmon (Bristol)</td>
<td>22</td>
<td>1 (1)</td>
<td></td>
<td></td>
<td></td>
<td>0</td>
</tr>
<tr>
<td>L. Safrany (Münster)</td>
<td>344</td>
<td>1 (1)</td>
<td>9 (1)</td>
<td>8 (6)</td>
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<td></td>
<td>0</td>
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<td>D. S. Zimmon (New York)</td>
<td>46</td>
<td>4 (2)</td>
<td></td>
<td></td>
<td></td>
<td>0</td>
</tr>
<tr>
<td>Totals</td>
<td>1107</td>
<td>37 (10)</td>
<td>15 (4)</td>
<td>22 (12)</td>
<td>20 (1)</td>
<td>12</td>
</tr>
</tbody>
</table>

(= 1.08%)

Numbers in parentheses: surgical treatment of complications.
frequently met with, which itself is an indication for papillotomy; in addition, it must not be forgotten that the damage to the papilla can be kept to a minimum by matching the length of the diameter of the stone. Late complications after endoscopic papillotomy are not yet known; possible complications might be an ascending infection of the pancreatic and bile duct system or secretory disturbances of the pancreas and the liver. At the present time, however, there are not enough long-term results to permit an accurate assessment of this point. Late follow-up examinations after surgical papillotomy have shown that the ‘bile transport’ function of the papilla is preserved, while its ‘valve’ function, which serves as a protection against duodenal reflux, is lost. Despite this duodenal reflux, however, which is observed in 60% of the cases, these patients rarely manifest an ascending cholangitis or pancreatitis.

In view of the fact that long-term results are not yet available, it is desirable for the present to limit endoscopic papillotomy to patients for whom surgery represents an increased risk. A list of indications was worked out in cooperation between German endoscopists and surgeons during a conference held in Frankfurt in October 1975:

1. Isolated papillary stenosis, diagnostically verified by clinical and laboratory sign of cholestasis, the distension of the extra- and intrahepatic biliary ducts and, if possible, manometric evidence of an increased duodenobiliary pressure gradient.

2. Common bile duct stones that were either overlooked on the occasion of one or more surgical operations on the biliary tract or are newly formed. In the case of younger patients (under 50 years of age) presenting with an intact papilla of Vater, the surgeons believe that a surgical choledochotomy is preferable in order to preserve the function of the papilla.

3. Common bile duct stones with symptoms of obstruction in patients at high surgical risk; in these cases, endoscopic papillotomy may be carried out, even though the patient has not previously subjected to a cholecystectomy.

Retained common bile duct stone—what to do?

After a choledocholithiasis has been diagnosed the next therapeutic procedure depends on whether a T-tube is still in situ or not. If it is, the dissolution of the gallstone or the mechanical extraction of the stone, either through the T-tube or transduodenally by endoscopic papillotomy, is recommended. According to Way the preferred method should be the mechanical extraction through the channel of the fistula of the T-tube by means of the Burhenne catheter. He found that it was an efficient (stone extraction in 95% of the cases), low-risk, and economical (because ambulatory) method of treatment. Next, an attempt should be made to dissolve the gallstone with cholate or heparin lavages. Unfortunately, this would involve the patient in at least a fortnight’s stay in hospital and there is the problem of the hardly controllable diarrhoea to which the procedure may give rise. Moreover, we, and other authors, have not found the procedure to be particularly effective. Only after both of these therapeutic ventures have failed should the bile duct stones be removed by the more invasive endoscopic papillotomy. In practice, however, personal experience, as well as the availability of method and technique, will be the decisive factor.
Non-surgical removal of common bile duct stones

In the absence of a T-tube one can choose between surgery and endoscopic papillotomy. As far as present practice on the European continent is concerned endoscopic papillotomy with stone extraction from the common bile duct will certainly be in future the method of choice, at least for patients with a high surgical operative risk.

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