Extracorporeal Shockwave Lithotripsy of Gallstones
Possibilities and Limitations

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Recently extracorporeal shockwave lithotripsy (ESWL) has been introduced as a nonoperative treatment for gallstone disease. Except for lung damage, no significant adverse effects of ESWL of gallbladder stones have been observed in animals. In clinical use ESWL of gallbladder stones is now confined to 15% to 30% of symptomatic patients. To achieve complete stone clearance, ESWL of gallbladder stones must be supplemented by an adjuvant therapy. ESWL of bile duct stones is highly effective and can be considered in patients in whom primary endoscopic or surgical stone removal fails. Second generation lithotriptors allow anesthesia-free (outpatient) treatments, but the clinical experience with most of these ESWL devices is still limited. The likelihood of gallbladder stone recurrence is a major disadvantage of ESWL treatment, which raises the issue of cost-effectiveness. ESWL for cholecystitis is a promising treatment modality with good short-term and unknown long-term results.

Extracorporeal shockwave lithotripsy (ESWL) has revolutionized therapy of urolithiasis. Despite concern about the long-term effectiveness and possible inducement of hypertension,1 this noninvasive treatment has gained worldwide acceptance. After the convincing success of ESWL in urology, it was tempting to extend this technology to the treatment of gallstones.

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Gallstone disease represents an important health care problem in the western world. The estimated prevalence of gallstones is about 10% to 15% and increases with advancing age.2 Although many gallstones do not cause symptoms and need not be treated,3-5 gallstone disease is a major cause of hospitalization for surgical treatment. In the United States annually more than $1 billion is spent on treatment of gallstones, mainly for the 500,000 cholecystectomies performed each year.6 Since Langenbuch performed the first cholecystectomy in Berlin in 1882,7 operative removal of the gallbladder has become the standard therapy for patients with symptomatic gallbladder stones. Cholecystectomy has an overall mortality rate of 0.6% to 1.3%, increasing from 0.2% in patients younger than 70 years to 5% in patients older than 70 years.8-11 A safe and effective treatment for many patients, the morbidity rate of cholecystectomy is 10% to 33%,11,12 it is uncomfortable for the patient, it requires hospitalization, and usually causes invalidity for 1 month.13 To reduce the morbidity and mortality rates, as well as the cost, several nonoperative therapeutic alternatives have become

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565
available for both cholecystolithiasis and choledocholithiasis. Although still in its infancy, ESWL of gallstones is one of the most promising noninvasive treatment modalities for cholelithiasis. In this review article we will discuss the possibilities and the limitations of ESWL for the management of gallstone disease.

**Principle of Shockwave Application**

The basic physical principles have been described in detail elsewhere, and presently only the essential clinical facts have been compiled. Shockwaves cause high pressure amplitudes to increase within nanoseconds and to respond to the known physical laws of acoustics. If water is used as a transmission medium, focused shockwaves spread through the body evenly without severely damaging the tissues because the acoustical impedance of most body tissues is close to that of water. At its focus point, the wave impact against the stone liberates short-term high-energy mechanical stresses because of the abrupt change in acoustical impedance. This causes tear-and-shear forces, which, together with the formation of cavitation bubbles in the surrounding medium on the surface of the stone, eventually lead to the disintegration of the stone.

The original waterbath lithotriptor developed by Dornier generates shockwaves by an underwater electric spark discharge in the one focus of an elliptical reflecting cavity that are condensed in the second focus. Positioning of the stone in this second focus occurs with a fluoroscopic guidance system. Today a second generation of ESWL devices is on the market, with the same concept of underwater generation of shockwaves (Table 1). They apply varying combinations of techniques for shockwave generation, focusing, and target imaging apparatus. Most manufacturers have replaced the water immersion tank with a compressible water bag that enables contact skin positioning of the shockwave applicator. Nearly all are more compact in design, operate at lower costs, require simpler patient positioning, and many have the potential capability for treating gallbladder stones.

**Experimental Application of ESWL**

Abdominal shockwave exposition in rats, as well as exposure of ventralated isolated organs (liver, kidney, intestine), did not cause pathologic changes. Shockwaves directed to kidneys or to implanted stones in the renal pelvis of pigs and dogs produced only slight and predominantly transient traumatization of the exposed kidneys. These dose-dependent alterations (small hematomas and/or diffuse intraparenchymal hemorrhages) are restricted to the high-pressure field of the shockwaves and do not affect renal function.

In acute experiments on dogs, shockwaves on the liver and gallbladder also caused slight changes: small ecchymoses on the liver surface and gallbladder wall. Petechial hemorrhages may also occur on the serosal surface of the pancreas and duodenum. These minor gross and histologic changes were not considered a contraindication to applying shockwaves for gallstone destruction in humans.

*On the other hand, if shockwaves strike on a tissue-air interface, in the lung, for example, damage may occur due to release of energy caused by the large difference in acoustical impedance of air and water.*

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**Table 1. Second Generation Extracorporeal Lithotriptors (Adapted from Ferrucci and updated to October 1988)**

<table>
<thead>
<tr>
<th>Manufacturer</th>
<th>Model</th>
<th>Shockwave Generation</th>
<th>Focusing</th>
<th>Target Imaging</th>
<th>Coupling</th>
<th>Suitability</th>
</tr>
</thead>
<tbody>
<tr>
<td>Wolf (W. Germany)</td>
<td>Piezolith 2300</td>
<td>PE</td>
<td>spherical array</td>
<td>US</td>
<td>mini-tank</td>
<td>GB</td>
</tr>
<tr>
<td>Technomed International (France)</td>
<td>Sonolith 3000</td>
<td>SGE</td>
<td>ellipsoid</td>
<td>US</td>
<td>mini-tank</td>
<td>GB</td>
</tr>
<tr>
<td>EDAP (France)</td>
<td>LT 01</td>
<td>PE</td>
<td>spherical array</td>
<td>US</td>
<td>waterbag</td>
<td>GB</td>
</tr>
<tr>
<td>Siemens (W. Germany)</td>
<td>Lithostar</td>
<td>EM</td>
<td>acoustic lens</td>
<td>x-ray</td>
<td>waterbag</td>
<td>CBD</td>
</tr>
<tr>
<td></td>
<td>Lithostar Plus</td>
<td>EM</td>
<td>acoustic lens</td>
<td>x-ray + US</td>
<td>waterbag</td>
<td>GB + CBD</td>
</tr>
<tr>
<td>Medstone International (USA)</td>
<td>1050 ST</td>
<td>SGE</td>
<td>ellipsoid</td>
<td>x-ray ± US</td>
<td>waterbag</td>
<td>GB</td>
</tr>
<tr>
<td>Nitech (Denmark)</td>
<td>HM 4</td>
<td>SGE</td>
<td>ellipsoid</td>
<td>x-ray</td>
<td>waterbag</td>
<td>GB</td>
</tr>
<tr>
<td>Dornier Medizin</td>
<td>MPL 9000</td>
<td>SGE</td>
<td>ellipsoid</td>
<td>US</td>
<td>waterbag</td>
<td>GB</td>
</tr>
<tr>
<td>Technik (W. Germany)</td>
<td>MFL 5000*</td>
<td>SGE</td>
<td>ellipsoid</td>
<td>x-ray</td>
<td>waterbag</td>
<td>GB</td>
</tr>
<tr>
<td>Direx (Israel)</td>
<td>Tripter X1</td>
<td>SGE</td>
<td>ellipsoid</td>
<td>x-ray + US</td>
<td>waterbag</td>
<td>GB + CBD</td>
</tr>
<tr>
<td>Northgate (USA)</td>
<td>SD 3</td>
<td>SGE</td>
<td>ellipsoid</td>
<td>US</td>
<td>waterbag</td>
<td>GB</td>
</tr>
<tr>
<td>Diasonics (USA)</td>
<td>Therasonic</td>
<td>PE</td>
<td>spherical array</td>
<td>x-ray + US</td>
<td>waterbag</td>
<td>GB + CBD</td>
</tr>
<tr>
<td>Storz Medical (W. Germany)</td>
<td>Modulith SL 10</td>
<td>PE</td>
<td>spherical array</td>
<td>x-ray + US</td>
<td>waterbag</td>
<td>GB + CBD</td>
</tr>
<tr>
<td></td>
<td>Modulith SL 20</td>
<td>PE</td>
<td>spherical array</td>
<td>x-ray + US</td>
<td>waterbag</td>
<td>GB + CBD</td>
</tr>
</tbody>
</table>

* Also marketed as Philips MFL 5000 (The Netherlands)
tissue. When the rat thorax was exposed to shockwaves, fatal lung damage was found.\textsuperscript{15,19,20} ESWL of surgically implanted gallbladder stones in dogs also resulted in pulmonary damage (alveolar hemorrhage) involving areas just above the diaphragm in one third of the animals;\textsuperscript{29} no animal died, and no hemoptysis was noted after shockwave application (Delius, written personal communication, 1988). These serious side effects are dependent on the shockwave pressure field. They do not occur when the lungs are more than 4 cm removed from the shockwave axis.\textsuperscript{30} Other investigators have observed no changes or lesions in the right lung only in dogs autopsied one day after ESWL; no changes were observed in animals killed 14 days after treatment.\textsuperscript{26,31} The differences in outcome of shockwave application can be explained by differences in shockwave pressure distribution in the acoustic fields generated by the various lithotriptors.

Differences in the physical characteristics of shockwave pulses generated by differing lithotriptors are also responsible for the variation in results of \textit{in vitro} fragmentation studies of human gallstones.\textsuperscript{32} Soft cholesterol stones with a low density, as assessed by computed tomography, required more discharges to fragment the stone than those with a high pigment and calcium content.\textsuperscript{33,34} On the other hand, other studies revealed successful fragmentation regardless of the chemical composition or the calcium content of the stone and suggest that ESWL may be applied to all types of gallstones. The effectiveness of this therapy will then only be limited by the total stone burden and the time required to complete stone fragmentation. This corresponds well with the observation that the number of shockwaves required to bring about fragmentation of human gallstones \textit{in vitro} correlated closely with the number, volume, weight, and diameter of the stones.\textsuperscript{31,35–38}

**Clinical Application of ESWL for Gallstones**

**Gallbladder Stones**

The first successful ESWL treatment of patients with gallstones was reported by Sauerbruch and coworkers in 1986.\textsuperscript{39} They treated nine patients with functioning gallbladders containing 1 to 3 symptomatic radiolucent stones that were not larger than 25 mm in diameter. All stones were disintegrated into sludge or fragments. At present more than 1000 patients with gallbladder stones, most of them in Germany, have undergone ESWL on different systems (Table 2). The selection of patients is usually determined according to the inclusion and exclusion criteria of the Munich group (Table 3).

Because only cholesterol stone fragments are susceptible to adjuvant dissolution therapy, patients with radiopaque, calcified stones have been excluded, with a few exceptions.\textsuperscript{46–48}

Recently the results of the first 175 patients treated in Munich were published.\textsuperscript{40} In this the best-documented series so far, 72% of patients with solitary stones 21 to 30 mm in diameter and 63% of those with two or three stones could be expected to be free of stones 1 year after lithotripsy and adjuvant oral dissolution therapy. Smaller stones disintegrated into smaller fragments than did larger stones. The success rate for single stones 20 mm or smaller in diameter was clearly higher than for larger and multiple stones. The disappointing results with multiple stones may be due to difficulties in sonographic identification of residual stones during ESWL treatment after disintegration of the first stone. The subsequent disintegration of the remaining stones may be less complete, resulting in larger residual fragments, the dissolution of which take a longer period. Although stones with a radiopaque rim could also be successfully disintegrated, more time was required for these stone fragments to disappear.

Complications have been few. Except asymptomatic petechiae at the entrance of shockwaves into the skin and incidental transient gross hematuria due to passage of shockwaves through the right kidney, no other adverse effects related to the administration of shockwaves were observed. Routine laboratory blood tests showed no significant changes, except a mild leucocytosis immediately after ESWL that normalized within 24 hours. Probably as a result of the passage of fragments, mild or moderate pancreatitis developed in two patients. Furthermore about one third of the patients suffered once or more frequently from mild biliary colicky pain, which was easily treated with spasmyltic agents. With the exception of diarrhea occurring in 4% of the patients, the adjuvant administration of oral bile acids did not cause adverse effects.

**Biliary Duct Stones**

The original clinical work done by Sauerbruch et al.\textsuperscript{39} also suggested that common bile duct stones may be fragmented by ESWL without causing serious side effects. Subsequently their experience has been further extended and similar positive results of ESWL of common duct, intrahepatic, and retained cystic duct stones with both first and second generation lithotripsy devices have been accumulated in a number of patient series. ESWL of biliary duct stones in 346 patients resulted in an overall complete stone clearance rate of 63% to 100% (Table 4).

Most patients with bile duct stones that resist removal after endoscopic sphincterotomy can be treated by ESWL without general anesthesia; and ESWL may resolve life-threatening conditions, especially for high-risk and critically ill patients.\textsuperscript{53,57,58} Significant adverse effects and alterations in laboratory tests, including liver and pancreas enzymes, usually do not occur. Transient hematuria is a
<table>
<thead>
<tr>
<th>First Author and References</th>
<th>No. of Patients</th>
<th>Type of Lithotriptor</th>
<th>Fragmentation (% of pts)</th>
<th>Adjuvant Treatment</th>
<th>Side Effects (%) of pts</th>
<th>Mean Follow-up</th>
<th>Stone free (% of patients)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sackmann et al.</td>
<td>175–250</td>
<td>Dornier-HM 3 (modified)</td>
<td>99</td>
<td>Urso + cheno*</td>
<td></td>
<td></td>
<td>80 post-ESWL</td>
</tr>
<tr>
<td>Heberer et al. (Munich)</td>
<td></td>
<td>Dornier-MPL 9000</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Greiner et al. (Wuppertal)</td>
<td>157</td>
<td>Dornier-HM 3 (modified)</td>
<td>94</td>
<td>Urso + cheno</td>
<td></td>
<td></td>
<td>70–80 expected to be stone free at 12 months post-ESWL</td>
</tr>
<tr>
<td>Ponchon et al. (Lyon)</td>
<td>91</td>
<td>Technomed Sonolith 2000/3000</td>
<td>71</td>
<td>Urso + cheno</td>
<td></td>
<td></td>
<td>50 post-ESWL</td>
</tr>
<tr>
<td>Pizzi et al. (Milano)</td>
<td>29</td>
<td>Siemens Lithostar</td>
<td>86</td>
<td>Urso</td>
<td>3 (n = 1)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Hood et al. (London)</td>
<td>38</td>
<td>Wolf Piezolith 2200/2300</td>
<td>89</td>
<td>Urso + cheno</td>
<td>11 (n = 1)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Manfredi et al. (Rome)</td>
<td>44</td>
<td>Technomed Sonolith 3000</td>
<td>80</td>
<td>Urso</td>
<td>No severe complications</td>
<td>4 months</td>
<td></td>
</tr>
<tr>
<td>Bory et al. (Lyon)</td>
<td>20</td>
<td>Tripter Direx-X1</td>
<td>75</td>
<td>Urso + cheno</td>
<td>No complications</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Darzi et al. (Dublin)</td>
<td>37</td>
<td>EDAP-LT 01</td>
<td>—</td>
<td>Bile acids (?)</td>
<td>3 (n = 1)</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

*Urso = Ursodiol, cheno = Chenodiol

**Note:** The table includes results of ESWL (extracorporeal shock wave lithotripsy) for gallbladder stones. The data are presented as frequency percentages for various side effects and complications, along with mean follow-up times and stone-free rates.
common finding after ESWL of bile duct stones but is of little clinical significance.

Limitations of Biliary ESWL

Initially lithotripsy of gallstones was performed under general anesthesia, limiting ESWL to patients with a preoperative physical status compatible with class I or II of the American Society of Anesthesiologists.39,59 Now intravenous analgesia is sufficient for most patients, general or epidural anesthesia seldom being required. Treatments with piezoelectric lithotripsy devices are reported to be completely painless.26,27,45 Nevertheless, depending on the type of lithotriptor, for certain patients intravenous opiate analgesia cannot replace adequate anesthetic techniques and the cooperation of an anesthesiologist (Schelling et al., unpublished data). Besides, unless triggered by the R-wave of ECG, the spark-gap systems especially can induce arrhythmias. Careful monitoring of the ECG is required, especially in patients with pre-existing cardiac rhythm disorders.

Anesthesia-free (outpatient) treatments have been made possible by lowering the total shockwave energy and by distributing the energy more diffusely at the skin surface. However the price for these technical adjustments is a lower initial stone fragmentation rate. For that reason more shockwaves are required, causing a longer duration of the treatment session or resulting in a high retreatment rate because patient tolerance is limited.

In contrast to kidney stones most gallstones are radiolucent. Fluoroscopic targeting of a nonopaque gallbladder stone is not possible unless the stone has been visualized by contrast opacification of the gallbladder by oral or intravenous cholecystography. Therefore targeting of gallbladder stones can be best accomplished by ultrasound, but this can be difficult or impossible in obese patients.

Gallbladder Stones

Several distinctions immediately arise between lithotripsy of gallbladder stones and urinary tract calculi.18 After ESWL at least 90% of fragments of renal calculi pass spontaneously through the ureter. Complete spontaneous discharge of residual fragments after ESWL of gallbladder stones cannot be expected because sufficient disintegration can rarely be obtained. This is crucial because experimental and clinical investigations indicate that only fragments smaller than 2 mm to 3 mm in diameter can pass into the intestine without causing local trauma.60,61 Besides, both the spiral valves in the cystic duct and the choledochoduodenal sphincter are anatomical barriers presenting potential sites of relative obstruction. Furthermore the common bile duct has no peristalsis and there is a pre-existing relative dysmotility of the gallbladder that is not altered by ESWL treatment.62,63 These factors imply
that in addition to biliary colic, cholecystitis, cholangitis, and pancreatitis are possible serious complications.

**Adjuvant therapy.** The need for adjuvant treatment after ESWL of gallbladder stones has not been absolutely proved and is being investigated in the United States in a randomized clinical multicenter trial. For now it is likely that successful therapy of gallbladder stones will require a combination of ESWL and a subsequent adjuvant therapy to achieve complete stone clearance. This can be performed in three ways: (1) the use of oral dissolution therapy with bile acids (only cholesterol stones),64 (2) percutaneous contact dissolution by direct transcatheater infusion into the gallbladder of solvents, the most promising of which is methyl-tert-butyl-ether (MTBE) (only cholesterol stones),65,66 and (3) percutaneous drainage for evacuating the gallbladder (cholesterol and pigment stones).67,68 Thus far bile acids have been used mainly as adjuvant management because they seem to offer the most simple and harmless treatment for remaining fragments of cholesterol stones. This implies that the nature of the stone must be known.

Dissolution by oral (or local) agents is greatly enhanced by preceding stone fragmentation.61,65-71 Despite this enhancement the expensive oral dissolution therapy still must be continued for at least 6 to 12 months after primary therapy by ESWL. Therefore, notwithstanding the more invasive character, adjuvant percutaneous dissolution therapy might afford a favorable alternative.47,72-74 For patients with large or numerous stones currently being excluded for ESWL treatment, contact dissolution with MTBE may broaden the applicability of ESWL. Moreover MTBE also seems to be useful after ESWL of partially calcified cholesterol stones.47

With pigment stones a combination of ESWL and a percutaneous evacuation technique, with which stone fragments are removed mechanically or by aspiration, is possible.67,68 Further development of solvents for contact dissolution of pigment stones may also be a future possibility.75-77

**Tissue damage.** On anatomical grounds the pulmonary damage found in dogs should present less of a problem in humans and such damage has not yet been observed in patients.29,31,40 Nevertheless ESWL has the potential for causing significant soft-tissue damage in the high-pressure area of the shockwaves around the focus.25,27,78 Patients subjected to ESWL immediately before elective cholecystectomy have shown gross evidence of acute tissue injury at laparotomy. Oedema of the gallbladder wall together with vascular dilatation, several petechial hemorrhages, and variable mucosal denudation were found (Johnson et al., unpublished data).27,78 With the exception of the mucosal denudation, these changes were absent from gallbladders excised 24 to 48 hours and 5 days after ESWL, which indicates that these changes may be rapidly reversible.45 The presence of intact epithelium in the mouths of the mucosal crypts, as visualized by scanning electron microscopy, may serve as a source of viable cells for re-epithelialization. Multiple small hematomas, which can be detected in the parts of the liver parenchyma which are transversed by the shockwaves, disappear within a few days to 4 weeks.25 These changes, which are comparable to the small perirenal and intraparenchymal hematomas observed after ESWL of kidney stones, are of no clinical importance.25,79-82 However this implies that patients with coagulation disorders should be excluded from ESWL treatment. Relying on the data presented in Table 2, the incidence of pancreatitis, which can be considered an adverse effect of the administration of shockwaves as well as a complication due to passage of fragments, is small. This finding is rather surprising because the risk of acute pancreatitis is said to be increased in patients with micro lithiasis of the gallbladder.83 Thus far emergency cholecystectomy for acute cholecystitis has not been reported. Finally gas-filled intestines may cause ESWL-induced erosions in the upper gastrointestinal tract.84

**Indications.** Application of ESWL is limited to only 15% to 30% of patients with symptomatic gallbladder stones who are referred for therapy.40,85 However the previously accepted selection criteria for ESWL of gallbladder stones (Table 3) seem to underestimate the number of suitable patients. Patients with stones larger than 30 mm in diameter, with more than three in number, and partially calcified stones have also been treated successfully, but in light of the lower success rate other treatments may be more attractive. As to the mere histopathologic status, 60% of cholecystectomized patients who have no or very limited histologic changes in the gallbladder are potential candidates for ESWL.86 In view of the diminishing need for anesthesia, it seems justified to extend this treatment to poor-surgical-risk patients, as recently reported.53,57,58 Increasing experience and further improvement of lithotriptors may make ESWL of gallbladder stones possible for a larger population of patients. For now, however, it

<table>
<thead>
<tr>
<th>Inclusion Criteria</th>
<th>Exclusion Criteria</th>
</tr>
</thead>
<tbody>
<tr>
<td>History of biliary pain</td>
<td>Acute cholecystitis, cholangitis, or pancreatitis</td>
</tr>
<tr>
<td>Solitary radiolucent gallbladder stone ≤ 30 mm, or up to three stones with similar total volume</td>
<td>Biliary obstruction or known bile duct stone</td>
</tr>
<tr>
<td>Gallbladder visualization by oral cholangiography</td>
<td>Coagulopathy or anticoagulants or aspirin</td>
</tr>
<tr>
<td>Stone positioning possible in the shockwave focus</td>
<td>Aneurysms or cysts in shockwave path</td>
</tr>
<tr>
<td>Shockwave avoids lung and bone</td>
<td>Pregnancy</td>
</tr>
</tbody>
</table>
is unlikely that gallbladder lithotripsy will equal ESWL in urology, which is now the standard treatment for urolithiasis for almost all patients.

**Stone characteristics.** For lithotripsy of gallbladder stones it is not sufficient to know whether gallstones are present or absent. At least the number and size of the gallstones must be known and cystic duct patency must be assessed. Plain abdominal x-rays are of limited value in predicting gallstone type because there is a 14% chance that radiolucent stones are pigment stones. As the fragments of pigment stones cannot be dissolved with the agents in use so far, it is important to predict gallstone composition more precisely. Computed tomography seems to be of great value in discriminating between radiolucent cholesterol and pigment stones, and thus in the prediction of susceptibility to adjuvant dissolution therapy. The exact role of this and other tests in differentiating between cholesterol and pigment stones has not yet been established. Before ESWL of patients with gallbladder stones is performed, an extension of the di-

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**Table 4. Results of ESWL of Biliary Duct Stones**

<table>
<thead>
<tr>
<th>First Author and References</th>
<th>No. of Patients</th>
<th>Location of Stones</th>
<th>Type of Lithotriptor</th>
<th>Complete Stone Fragmentation (% of pts)</th>
<th>Complete Stone Clearance (% of pts)</th>
<th>Side Effects</th>
<th>% of Patients</th>
</tr>
</thead>
<tbody>
<tr>
<td>Heberer* (Munich)</td>
<td>51</td>
<td>common bile duct</td>
<td>Dornier-HM 3</td>
<td>—</td>
<td>80</td>
<td>not documented</td>
<td></td>
</tr>
<tr>
<td>Sauerbruch* (multicenter trial)</td>
<td>113</td>
<td>(common) bile duct</td>
<td>Dornier-HM 3</td>
<td>1 treatm: 86 ≥ 2 treatm: 91</td>
<td>86 mild</td>
<td>mortality* 29</td>
<td></td>
</tr>
<tr>
<td>Greiner† (Wuppertal)</td>
<td>36</td>
<td>(common) bile duct</td>
<td>Dornier-HM 3</td>
<td>—</td>
<td>97 sepsis (n = 1)</td>
<td>3</td>
<td></td>
</tr>
<tr>
<td>Staritz‡ (Mainz)</td>
<td>30</td>
<td>intrahepatic (5) common bile duct (25)</td>
<td>Siemens Lithostar</td>
<td>intrahepatic: 100 common bile duct: 70</td>
<td>—</td>
<td>cutaneous petechiae</td>
<td></td>
</tr>
<tr>
<td>Burhenne (Vancouver)</td>
<td>8</td>
<td>common bile duct (4) cystic duct (remnant) (4)</td>
<td>Dornier-HM 3</td>
<td>75</td>
<td>75 short term fever (n = 3) mild hematuria (n = 2) transient hemobilia (n = 1)</td>
<td>38 25 13</td>
<td></td>
</tr>
<tr>
<td>Burhenne†</td>
<td>30</td>
<td>(common) bile duct</td>
<td>Siemens Lithostar</td>
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<td>±75</td>
<td>not documented</td>
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<tr>
<td>Terpstra‡ (Rotterdam)</td>
<td>13</td>
<td>common bile duct</td>
<td>Dornier-HM 3</td>
<td>100</td>
<td>100 transient hematuria small subcapsular hematoma of right kidney (n = 2) sepsis (n = 1) cutaneous petechiae (n = 1)</td>
<td>77 15 8 13</td>
<td></td>
</tr>
<tr>
<td>Terpstra†</td>
<td>8</td>
<td>common bile duct</td>
<td>Siemens Lithostar</td>
<td>63</td>
<td>63</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Faustini‡ (Milano)</td>
<td>14</td>
<td>(common) bile duct</td>
<td>Siemens Lithostar</td>
<td>100</td>
<td>100 none</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Ginestal-Cruz† (Lisbon)</td>
<td>16</td>
<td>(common) bile duct</td>
<td>Siemens Lithostar</td>
<td>69</td>
<td>69 cutaneous petechiae</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Bory† (Lyon)</td>
<td>11</td>
<td>common bile duct</td>
<td>Direx Tripter-X1</td>
<td>91</td>
<td>91 not documented</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Fried‡ (Halifax)</td>
<td>16</td>
<td>(common) bile duct</td>
<td>Dornier-HM 3</td>
<td>94</td>
<td>88 transient hemobilia (n = 2) short-term elevation of AST and LDH transient hematuria (n = 1) cutaneous petechiae</td>
<td>12 6 81 most patients</td>
<td></td>
</tr>
</tbody>
</table>

* Mortality = 30 day mortality.
† Personal communication, biliary lithotripsy; First International Symposium, July 11–13, 1988, Boston.

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**Vol. 201 - No. 5**

**EXTRACORPOREAL SHOCKWAVE LITHOTRIPSY OF GALLSTONES**

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**Vol. 201 - No. 5**
agnostic work-up is needed. Sonography should be combined with the almost-obsolete-but-now-reviving method of oral cholecystography to establish the functional status of the gallbladder.

Reurrence. A significant drawback of each alternative for cholecystectomy and also of ESWL of gallbladder stones lies in the likelihood of stone recurrence. Although recurrence after ESWL has not been definitely assessed due to the relatively short follow-up period, experience with oral bile acid dissolution therapy suggests a 50% recurrence rate within 7.5 years after complete disappearance of stone fragments.49,50 This corresponds with the observed recurrence rate of 10% within 6 months after discontinuation of adjuvant dissolution therapy after preceding ESWL treatment.41 The feasibility, effectiveness, and potential toxicity of long-term continuous low-dose or intermittent therapeutic-dose treatment with bile acids to prevent stone recurrence have not been conclusively investigated.95,96 Oral administration of inhibitors of HMG-CoA reductase, however, may be an interesting treatment to decrease the cholesterol excretion in the bile, thus reducing the chance of recurrence of gallstone disease. To prevent recurrent stone formation, the results of attempts of nonsurgical defunctionalization of the gallbladder by percutaneous occlusion of the cystic duct and ablation of the gallbladder by sclerosing agents are currently being evaluated in experimental models.97-103 The results are promising and the first application in humans has recently been started (Becker, written personal communication, 1988).

Bile Duct Stones

Despite the potential of ESWL, the indications for ESWL treatment of bile duct stones will remain limited because there are other effective nonoperative treatment modalities such as endoscopic removal.104,105 Therefore shockwave fragmentation should be considered only in patients in whom, after endoscopic sphincterotomy, stone extraction fails. This represents only 9% of all patients with bile duct stones referred for endoscopic removal.50

Unlike gallbladder stones, common bile duct stones are preferably localized by fluoroscopy rather than sonography.106 To focus the shockwaves on the stone, bile duct stones have to be visualized, which is normally achieved by contrast injection through an endoscopically placed nasobiliary catheter.41,50 This can also be performed by percutaneous transhepatic cholangiography.53,54,56,107

A treatment failure rate of 20% at the first session must be accepted (Sauerbruch, written personal communication, 1988). Failure of lithotripsy could not be predicted by analysis of the calculi before ESWL by computed tomography and did not depend on stone diameter. Interposition of bowel gas, which is likely to absorb shockwave energy, is possibly responsible for failure of treatment.52 In approximately 75% of patients additional interventional procedures, like endoscopic extraction of remaining fragments, are needed to achieve complete fragment clearance.50

Problems and Perspectives

A number of problems still must be solved. A major question is how to measure efficacy of ESWL treatment of gallstones. Most reports mention fragmentation rates and/or stone clearance rates, but much obscurity still exists about the effects on symptoms. Thus far only symptomatic gallbladder stones have been treated. For comparison of the long-term results it would be desirable to use a clear definition of "symptomatic gallstones," as was recently established by a working party at the Gastroenterology Meeting in Rome.108 While for a silent (asymptomatic) stone in the gallbladder an expectant approach may be best, some form of active treatment has been recommended for asymptomatic choledocholithiasis.108

In the event of recurrence, retreatment with ESWL or dissolution therapy must be considered, although it is still uncertain if all recurrent stones will again cause symptoms. This raises the question whether ESWL as primary therapy for gallbladder stones is cost-effective, at least for young patients. Significant cost savings have been realized by hospital discharge 24 hours after cholecystectomy.109,110 For most of the healthy and relatively young patients, cholecystectomy, which provides a permanent cure at a small risk, remains the most cost-effective option. For patients older than 70 years, ESWL will probably be of greater importance because of the higher morbidity and mortality rates of surgical management. The possibility of ESWL treatment on an outpatient basis should also be taken into account. Analysis of the cost-effectiveness of lithotripsy of gallbladder stones versus conventional cholecystectomy requires further observations of long-term results. This goal can be best achieved in prospective randomized studies, which are being conducted in Sheffield, United Kingdom (Williams, written personal communication, 1988) and at our institution.

Although increasing steadily, experience with extracorporeal shockwave treatment of gallstones outside Germany is still limited, and the reports of results with second generation lithotriptors are based on small patient series. Most of these preliminary studies have only a short follow-up and are not well documented. The (adapted) Dornier renal lithotriptor has proved to be a device to treat gallstones in the gallbladder and in the common bile duct successfully without serious short-term adverse effects in selected patients. Thorough data on the potential risk of harmful side effects and efficacy of most second generation lithotripsy devices, however, are still lacking. Caution in the clinical application of new ESWL systems for treatment of cholelithiasis is mandatory. Basic experimental
work on the pressure distribution in the focal area as well as to safety and efficacy must be done for each new lithotripsy apparatus before human biliary application is justified.\textsuperscript{13}

In conclusion ESWL for gallstone disease is a promising noninvasive treatment modality with acceptable short-time risks and efficacy. Long-term results and possible late complications still must be assessed.

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